

US3812169 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:51:31

All time stamps listed in this document are displayed in GMT

US3812169

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

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[Participant ID](#)

US3812169

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

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US3812169

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3812169

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	OSTEOARTHRITIS BILATERAL KNEE
Start date (dd MMM yyyy)	11 AUG 2011
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)	AUG 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	UNILATERAL PERIPHERAL NEUROPATHY (RIGHT SIDE ONLY, SENSORY OR MOTOR IN NATURE UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	INFLUENZA STRAIN B
Start date (dd MMM yyyy)	06 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	15 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	15 MAY 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)	MAY 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	20 MAR 1982
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)	20 MAR 1982
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1982
Start Year (derived)	1982
Stop Month and Year (derived)	MAR 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	IRON DEFICIENCY INDUCED ANEMIA
Start date (dd MMM yyyy)	UN UNK 1974
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)	20 MAR 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	MAR 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	(R) HIP PAIN
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	FLAGYL ALLERGY (HIVES)
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	HEADACHES
Start date (dd MMM yyyy)	UN JAN 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	RECREATIONAL MARIJUANA USE
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

Condition	CHRONIC CONSTIPATION
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 (15)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:40
Height ( <i>xxx.x</i> )	67.1 in
Weight ( <i>xxx.x</i> )	187.0 lb
BMI ( <i>xxx.x</i> )	29.26216 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Date of assessment (dd MMM yyyy) 14 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) 15 MAY 2005

Date of last menstruation unknown False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:57:57

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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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186276

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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)	14 AUG 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:40
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:00
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 10:30

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	14 AUG 2020 10:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:25	14 AUG 2020 10:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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: 10 Jun 2021 09:51:31

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 11:39

PC Open Date & Time

14 AUG 2020 10:50

PC Close Date & Time

14 AUG 2020 13:20

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	15 AUG 2020 08:46
PC Open Date & Time	14 AUG 2020 14:15
PC Close Date & Time	15 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 21:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:27

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 14:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

18 AUG 2020 16:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 14:32

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 13:55

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**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

14 AUG 2020 11:40

PC Open Date & Time

14 AUG 2020 10:50

PC Close Date & Time

14 AUG 2020 13:20

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**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

15 AUG 2020 08:46

PC Open Date & Time

14 AUG 2020 14:15

PC Close Date & Time

15 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**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

15 AUG 2020 21:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**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

16 AUG 2020 14:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 14:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 14:32

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:55

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**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 ☐

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 11:41
PC Open Date & Time	14 AUG 2020 10:50
PC Close Date & Time	14 AUG 2020 13:20

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**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 ☐

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 08:47
PC Open Date & Time	14 AUG 2020 14:15
PC Close Date & Time	15 AUG 2020 11:59



US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 14:25
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 16:24
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59



US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 14:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 13:56
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3812169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3812169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:35
Temperature (xxx.x)	98.6 F
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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	17:50 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:50
Temperature (xxx.x)	97.5 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 17:15 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 17:15

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

US3812169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	17:05 (24 HR)
Collection date and time (derived)	11 SEP 2020 17:05



US3812169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:07	11 SEP 2020 17:07
Nasopharyngeal Swab 2	No		

US3812169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:49

PC Open Date & Time

11 SEP 2020 17:35

PC Close Date & Time

11 SEP 2020 20:05

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.8 °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	11 SEP 2020 21:00
PC Open Date & Time	11 SEP 2020 21:00
PC Close Date & Time	12 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 13:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 06:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:36

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**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

11 SEP 2020 17:50

PC Open Date & Time

11 SEP 2020 17:35

PC Close Date & Time

11 SEP 2020 20:05

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**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

11 SEP 2020 21:01

PC Open Date & Time

11 SEP 2020 21:00

PC Close Date & Time

12 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**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

12 SEP 2020 12:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**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

13 SEP 2020 13:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 19:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 06:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:37

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**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 ☐

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:50
PC Open Date & Time	11 SEP 2020 17:35
PC Close Date & Time	11 SEP 2020 20:05

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**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 ☐

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:02
PC Open Date & Time	11 SEP 2020 21:00
PC Close Date & Time	12 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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)

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:25
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:17
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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 ☒

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:35
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**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 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 06:37
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**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 ☒

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:37
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3812169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:57:58

Generated On: 10 Jun 2021 09:51:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3812169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:57:58

Generated On: 10 Jun 2021 09:51:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	16:21 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 16:21
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:57:58

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:57:58

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	16:55 (24 HR)
Collection date and time (derived)	12 OCT 2020 16:55

US3812169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:58

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 19:17:42

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 19:03:43
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

28 OCT 2020 19:37:48

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59



US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 06:37:43

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 19:02:14

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

23 NOV 2020 15:32:49

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

29 NOV 2020 10:11:30

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 11:41:07
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

15 DEC 2020 10:57:06

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

20 DEC 2020 09:07:43

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

28 DEC 2020 21:26:50

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59



US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

03 JAN 2021 09:52:19

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

13 JAN 2021 12:09:18

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

17 JAN 2021 10:22:28

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

26 JAN 2021 23:20:26

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

31 JAN 2021 09:16:48

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

09 FEB 2021 12:53:15

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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	17 FEB 2021 10:25:36
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 21:53:03
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59



US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

03 MAR 2021 11:06:29

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

08 MAR 2021 18:36:37

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

17 MAR 2021 11:29:10

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

21 MAR 2021 01:23:14

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

28 MAR 2021 10:20:31

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

04 APR 2021 06:54:01

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

11 APR 2021 00:15:10

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

21 APR 2021 09:27:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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

25 APR 2021 09:37:33

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 271

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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 <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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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 <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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	28 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 DEC 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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 <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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 621

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

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

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

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

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

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



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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="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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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="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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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"/>

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

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 ☐



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**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 ☐

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3812169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

**US3812169**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:51:31**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 11:06:13

US3812169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

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

Visit date (dd MMM yyyy)	08 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	16:23 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 16:23
Temperature ( <i>xxx.x</i> )	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812169

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:55:48

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 MAR 2021
Collection time (00:00-23:59)	16:35 (24 HR)
Collection date and time (derived)	08 MAR 2021 16:35



US3812169

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:55:48

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3812169

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3812169**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

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*

**US3812169**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Date of Contact	23 MAR 2021
Time of Contact	10:00
Date and Time of Contact (derived)	23 MAR 2021 10:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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"/>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	18 MAR 2021	
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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US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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"/>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	19 MAR 2021
------	-------------

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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 23 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	20 MAR 2021	
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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 23 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	21 MAR 2021	
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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" 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 23 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 23 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	22 MAR 2021
------	-------------

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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" 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 23 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 type="checkbox"/>
Day 6	<input checked="" 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 23 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	23 MAR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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 type="radio"/>
	Mild <input checked="" 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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" 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 23 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" 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 23 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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	24 MAR 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
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 type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 23 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" 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"/>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 MAR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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 type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 23 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" 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 23 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 MAR 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
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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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

	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 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"/>

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 08 Apr 2021 01:36:06

Generated On: 10 Jun 2021 09:51:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 08 Apr 2021 01:36:05

Generated On: 10 Jun 2021 09:51:31

Date of Visit	23 MAR 2021
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	23 MAR 2021
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

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3812169

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 MAR 2021
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)	

US3812169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

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

Folder OID	SICKD1
------------	--------

US3812169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:45 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 10:45
Height ( <i>xxx.x</i> )	67.0 in
Weight ( <i>xxx.x</i> )	182.3 lb
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812169

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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



US3812169

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 MAR 2021

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:36:05

Generated On: 10 Jun 2021 09:51:31

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

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:36:05

Generated On: 10 Jun 2021 09:51:31

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) \_\_\_\_\_

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:36:05

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 08 Apr 2021 01:36:05

Generated On: 10 Jun 2021 09:51:31

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3812169

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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

Visit date (dd MMM yyyy)	11 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3812169

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:55:48

Generated On: 10 Jun 2021 09:51:31

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

US3812169

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Height	67.1 in
Weight	187.8 lb
BMI (xxx.x)	29.38735



US3812169

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Height	67.1 in
Weight	187.8 lb
BMI (xxx.x)	29.38735
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:55
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Height	67.1 in
Weight	187.8 lb
BMI (xxx.x)	29.38735
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:53
Temperature (xxx.x)	97 F
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)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

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

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

11 FEB 2021

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

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US3812169

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

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 15:23 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 15:23

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

US3812169

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00-23:59)	14:40 (24 HR)
Collection date and time (derived)	11 FEB 2021 14:40

US3812169

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00 - 23:59)	14:45
Collection Date and Time (derived)	11 FEB 2021 14:45

US3812169

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

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3812169

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:57:57

Generated On: 10 Jun 2021 09:51:31

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

US3812169

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3812169

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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)	08 MAR 2021
Time of assessment (00:00-23:59)	16:23 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 16:23
Temperature (xxx.x)	98.8 F
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)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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)	08 MAR 2021
Time of assessment (00:00-23:59)	17:17 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 17:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3812169

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

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) 08 MAR 2021

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 08 MAR 2021 16:44

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

US3812169

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:55:47

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:55:48

Generated On: 10 Jun 2021 09:51:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3812169

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:55:48

Generated On: 10 Jun 2021 09:51:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812169

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

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

Visit date (dd MMM yyyy)	07 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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US3812169

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:43 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 13:43
Temperature ( <i>xxx.x</i> )	96.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812169

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

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.*

US3812169

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 20:05:36

Generated On: 10 Jun 2021 09:51:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 APR 2021
Collection time (00:00-23:59)	14:00 (24 HR)
Collection date and time (derived)	07 APR 2021 14:00

US3812169

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3812169

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 SEP 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812169

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

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



US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID	USA-US111-2021-MRNA-1273-P30 1000005
Adverse event	MULTIPLE FALLS
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)	17 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	07 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

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

US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

THIS IS A 67 YEAR OLD FEMALE WHO NOTIFIED SITE STAFF ON 12 JAN 2021, THAT SHE WAS ADMITTED TO THE HOSPITAL DUE TO FREQUENT FALLS ON 17DEC2020. SHE REPORTS SYMPTOMS OF LEFT SIDED WEAKNESS AND RIGHT HIP PAIN. SUBJECT HAS A PERTINENT HISTORY OF RIGHT TOTAL KNEE ARTHROPLASTY ON 04DEC2020, LEFT FOOT DROP SINCE 2013, AND LIVES ALONE. SHE HAD 2+ EDEMA UPON PHYSICAL ASSESSMENT TO THE RIGHT CALF. SUBJECT COMPLETED A CT SCAN OF HER HEAD ON 21DEC2020 AND NO HEMORRHAGE WAS FOUND. SHE COMPLETED AN X-RAY OF HER PELVIS AND RIGHT HIP THAT WAS UNREMARKABLE. SUBJECT DID HAVE AN ELEVATED D-DIMER 3.34. SUBJECT COMPLETED A RIGHT LOWER EXTREMITY ULTRASOUND THAT CONFIRMED NO DVT. SHE COMPLETED A CT OF THE PELVIS ON 22DEC2020 AND THAT WAS UNREMARKABLE. A URINALYSIS WAS OBTAINED AND POSITIVE FOR NITRITES AND 3+ LEUKOCYTES. URINE CULTURE WAS POSITIVE FOR E.

US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

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COLI. SHE WAS DISCHARGED  
WITH INSTRUCTIONS TO TAKE  
MACROBID 100MG TWICE A  
DAY. DUE TO LIVING ALONE  
AND RECENT KNEE  
REPLACEMENT, SHE WAS  
DISCHARGED TO A  
REHABILITATION FACILITY.  
RECORDS DO NOT INDICATE  
ANY COVID-19 TESTING WAS  
PERFORMED.

---

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

---

US3812169

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID

Adverse event

RIGHT SIDED SCIATICA

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)

21 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812169

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3812169

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID

Adverse event

DECREASED RANGE OF  
MOTION RIGHT KNEE (POST  
RTKA)

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)

25 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 13:34:36

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 13:34:36

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID	
Adverse event	POST OPERATIVE RIGHT KNEE 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)	05 DEC 2020
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 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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input 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 type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID

Adverse event

RHINOVIRUS/ENTEROURUS  
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (8)

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

AEID	USA-US111-2021-MRNA-1273-P30 1000005
Adverse event	URINARY TRACT INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	28 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 13:34:36

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

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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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication ZOLPIDUM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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 (2)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication GABAPENTEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SIDED UNILATERAL  
PERIPHERAL (BOTH LIMBS)  
NEUROPATHY

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 (2)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication MYRBETRIQ

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

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 (3)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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 NOV 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 (4)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication MACROBID

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication BUTALBITAL/ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

Dose per administration 50/300

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:45:32

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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 JAN 2017	
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 (6)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
KNEE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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 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)		
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 (7)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PROPHALACTIC

Dose per administration 1

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

If dose unit is Other, specify DOSE

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) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication POST OP PAIN-RIGHT TOTAL  
KNEE REPLACEMENT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

PRN BID

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 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 (9)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication SENNA

Prophylaxis Yes ☒  
No ☐

Indication OPIOID INDUCED  
CONSTIPATION

Dose per administration 8.6

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 (9)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 DEC 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 (10)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication POST-OP PAIN (RIGHT TOTAL  
KNEE REPLACEMENT)

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 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 (11)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication POST OP PAIN RIGHT TOTAL  
KNEE REPLACEMENT

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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 (12)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication NITROFURANTOIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	18 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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 (13)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication THERAFLU [ACETAMINOPHEN,  
DIPHENHYDRAMINE,  
PHENYLEPHRINE]

Prophylaxis Yes ☐  
No ☒

Indication NASAL CONGESTION

Dose per administration 650/25/10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 MAR 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 (14)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication THERAFLU [ACETAMINOPHEN,  
DIPHENHYDRAMINE,  
PHENYLEPHRINE]

Prophylaxis Yes ☐  
No ☒

Indication NASAL CONGESTION

Dose per administration 650/25/10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAR 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 (15)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication WAL-PHED  
[PSEUDOEPHEDRINE]

Prophylaxis Yes ☐  
No ☒

Indication NASAL CONGESTION

Dose per administration 120

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 (15)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 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 (16)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication WAL-PHED  
[PSEUDOEPHEDRINE]

Prophylaxis Yes ☐  
No ☒

Indication NASAL CONGESTION

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 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"/>

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication MACROBID

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 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"/>

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication POST-OP PAIN RIGHT TOTAL  
KNEE REPLACEMENT

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 02:45:32

Generated On: 10 Jun 2021 09:51:31

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 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"/>

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:57:46

Generated On: 10 Jun 2021 09:51:31

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 13:34:36

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 DEC 2020	RIGHT TOTAL KNEE REPLACEMENT	Medical History	
03 MAR 2021	SCARRING DEBRIDEMENT	Adverse Event	
21 DEC 2020	CT OF HEAD	Adverse Event	
21 DEC 2020	ULTRASOUND OF RIGHT LOWER EXTREMITY	Adverse Event	
22 DEC 2020	CT OF PELVIS	Adverse Event	

US3812169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:51:31

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



US3812169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:31

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 ☐

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/JAN/2021 16:41
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

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/JAN/2021 07:30
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

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/FEB/2021 07:46
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

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/MAR/2021 13:52
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

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	14/APR/2021 06:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/APR/2021 10:43
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



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/APR/2021 16:24
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

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 13:34:37

Generated On: 10 Jun 2021 09:51:31

SAEID	USA-US111-2021-MRNA-1273-P301000005
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/APR/2021 08:07
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

US3812169 (Prod: Sundance Clinical Research - Platinum - PPDS)

**US3812169**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:51:31**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'US3812169'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:29

**US3812169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:37

**US3812169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:30

**US3812169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:37

**US3812169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'SCRN'	System	14 Aug 2020 15:50:37



**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:31

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '67'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'YEARS'	System	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '67'	System	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Female (F)'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'I'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54



**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:51:31**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	14 Aug 2020 15:50:54

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04



**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Aug 2020'	System	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2020'	System	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Amendment 2 (2)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:04

**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:30



**US3812169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:51:31**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'I'	System	14 Aug 2020 15:51:30

**US3812169**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:30

**US3812169**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:51:31**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:19:50

US3812169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 11:21:57
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	21 Sep 2020 16:35:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:44:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:44:51
Data point term sent to Coder	System	16 Sep 2020 13:44:07
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	16 Sep 2020 13:43:20
User entered 'OSTEOARTHRITIS BILATERAL KNEE' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	16 Sep 2020 13:43:20
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:43:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: OA knee - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:30:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:30:16
Data point term sent to Coder	System	17 Aug 2020 20:21:07
User entered 'OA (B) KNEE'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Aug 2011'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:20:08



**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Aug 2011'	System	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2011'	System	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:08

**US3812169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:08

US3812169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
Data point term sent to Coder	System	17 Aug 2020 20:21:07
User entered 'INSOMNIA'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 2016'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20



**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2016'	System	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2016'	System	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:20

**US3812169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:20

US3812169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 08:36:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 08:36:47
Data point term sent to Coder	System	24 Feb 2021 15:57:37
Coding entries removed.	lauren clement (b) (4) (b) (4)	24 Feb 2021 15:57:23
Signature has been broken.	lauren clement (b) (4) (b) (4)	24 Feb 2021 15:57:23
User entered 'UNILATERAL PERIPHERAL NEUROPATHY (RIGHT SIDE ONLY, SENSORY OR MOTOR IN NATURE UNKNOWN)' reason for change: New Information	lauren clement (b) (4) (b) (4)	24 Feb 2021 15:57:23
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:43:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:43:45
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:28:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:28:45



US3812169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
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)	11 Nov 2020 17:26:59
Data point term sent to Coder	System	27 Oct 2020 20:41:32
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.	Maureen Dempsey (b) (4)	27 Oct 2020 20:40:51
' answered with 'UPDATED PER SUBJECT PHONE CALL ' (Site from DM).	(b) (4)	
Coding entries removed.	Maureen Dempsey (b) (4)	27 Oct 2020 20:40:40
	(b) (4)	
User entered 'RIGHT SIDED PERIPHERAL (BOTH LIMBS) NEUROPATHY' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	27 Oct 2020 20:40:40
	(b) (4)	
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.	(b) (4), (b) (6)	23 Oct 2020 12:16:17
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:21:07
User entered 'NEUROPATHY'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2000'	System	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2000'	System	17 Aug 2020 20:20:33



**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:33

**US3812169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:33

US3812169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:22:11
Data point term sent to Coder	System	17 Aug 2020 20:21:07
User entered 'OVERACTIVE BLADDER'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN Nov 2019'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:20:50



**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Nov 2019'	System	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2019'	System	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:50

**US3812169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:20:50

US3812169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
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)	17 Aug 2020 23:18:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 23:18:21
Data point term sent to Coder	System	17 Aug 2020 20:22:08
User entered 'INFLUENZA STRAIN B'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '06 Jan 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19



**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15 Jan 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2020'	System	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2020'	System	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2020'	System	17 Aug 2020 20:21:19

**US3812169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2020'	System	17 Aug 2020 20:21:19

US3812169

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:23:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:23:14
Data point term sent to Coder	System	17 Aug 2020 20:22:08
User entered 'POST MENOPAUSAL'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15 May 2005'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39



**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'May 2005'	System	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2005'	System	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:21:39

**US3812169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:21:39



US3812169

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:23:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:23:14
Data point term sent to Coder	System	17 Aug 2020 20:22:11
User entered 'TUBAL LIGATION'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '20 Mar 1982'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '20 Mar 1982'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Mar 1982'	System	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1982'	System	17 Aug 2020 20:22:05



**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Mar 1982'	System	17 Aug 2020 20:22:05

**US3812169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1982'	System	17 Aug 2020 20:22:05

US3812169

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anaemia - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 23:21:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 23:21:23
Data point term sent to Coder	System	17 Aug 2020 20:23:11
User entered 'IRON DEFICIENCY INDUCED ANEMIA'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 1974'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '20 Mar 1982'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:39



**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 1974'	System	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1974'	System	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Mar 1982'	System	17 Aug 2020 20:22:39

**US3812169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1982'	System	17 Aug 2020 20:22:39

US3812169

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:47:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:47:11
Data point term sent to Coder	System	17 Aug 2020 20:23:12
User entered '(R) HIP PAIN'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 2011'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55



**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2011'	System	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2011'	System	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:22:55

**US3812169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:22:55

US3812169

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 00:00:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:00:50
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:38:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:38:22
Data point term sent to Coder	System	17 Aug 2020 20:24:13
User entered 'FLAGYL ALLERGY (HIVES)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 1998'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:21



**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 1998'	System	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1998'	System	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:21

**US3812169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:21



US3812169

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:25:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:25:17
Data point term sent to Coder	System	17 Aug 2020 20:24:13
User entered 'HEADACHES'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN Jan 2017'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2017'	System	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2017'	System	17 Aug 2020 20:23:39



**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:39

**US3812169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:39

US3812169

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Cannabis use - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:59:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:59:14
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Recreational substance use - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:52:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:52:49
Data point term sent to Coder	System	17 Aug 2020 20:24:14
User entered 'RECREATIONAL MARIJUANA USE'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 1982'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:23:58



**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 1982'	System	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '1982'	System	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:58

**US3812169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:23:58

US3812169

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:26:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:26:20
Data point term sent to Coder	System	17 Aug 2020 20:25:14
User entered 'CHRONIC CONSTIPATION'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'UN UNK 2010'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18



**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2010'	System	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2010'	System	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:24:18

**US3812169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	17 Aug 2020 20:24:18

US3812169

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:51:31

Condition

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Peroneal nerve palsy, LLT: Foot drop - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 16:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 16:49:40
Data point term sent to Coder	System	26 Apr 2021 16:47:33
User entered 'LEFT FOOT DROP'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'UN UNK 2013'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37



**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '0'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Yes (Y)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '0'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'Jan 2013'	System	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '2013'	System	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	26 Apr 2021 16:46:37

**US3812169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered empty.	System	26 Apr 2021 16:46:37



**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '09:40'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered '14 Aug 2020 09:40'	System	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '67.1' in	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58
DataPoint set to visible.	System	14 Aug 2020 15:51:30

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '187.0' lb	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58
DataPoint set to visible.	System	14 Aug 2020 15:51:30

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
Amendment Manager: User entered '29.26216'	System	16 Sep 2020 23:57:07
User entered '29.3'	System	17 Aug 2020 20:24:58
DataPoint set to visible.	System	14 Aug 2020 15:51:30

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'kg/m2'	System	17 Aug 2020 20:24:58
DataPoint set to visible.	System	14 Aug 2020 15:51:30



**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Other (Other)'	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'bpm'	System	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'breaths/min'	System	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58



**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'mmHg'	System	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User entered 'mmHg'	System	17 Aug 2020 20:24:58

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44

**US3812169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44

**US3812169**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:11

US3812169

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 18:40:27
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 22:42:40
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:11

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45



**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

**If Surgically sterile, date of surgery (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15 May 2005'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:51:31**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:25:45

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06



US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

[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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

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**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06



US3812169

Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

[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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'I'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06



US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

**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)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

US3812169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:25:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:26:06

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:40

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:40

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	14 Aug 2020 15:51:40

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'VISIT1'	System	14 Aug 2020 15:51:40



US3812169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:18

US3812169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:31:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:31:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 15:19:18
User entered '186276' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:18

US3812169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:18

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

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)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:36

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

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)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:36

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:36

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:36

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:36



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:51:31**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	21 Sep 2020 18:28:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:16:44

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '09:40'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '14 Aug 2020 09:40'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '96.9' F	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '78'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'bpm'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'breaths/min'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '110'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '72'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:28:25



US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:31:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 20:28:25
User entered '11:00'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25
	(b) (4)	

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '14 Aug 2020 11:00'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '97.1' F	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '75'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'bpm'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'breaths/min'	System	17 Aug 2020 20:28:25

US3812169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '112'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '70'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	17 Aug 2020 20:28:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:41



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:26:41

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

US3812169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '10:30'	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '14 Aug 2020 10:30'	System	14 Aug 2020 15:52:25



US3812169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'ONCE'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:50

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:50

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '10:20'	Breanna Galibert (b) (4)	17 Aug 2020 20:26:50

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '14 Aug 2020 10:20'	System	17 Aug 2020 20:26:50

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:27:02



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '10:25'	Breanna Galibert (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '14 Aug 2020 10:25'	System	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 20:27:02

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered empty.	System	17 Aug 2020 20:27:02



**US3812169**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:12:19

**US3812169**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	25 Aug 2020 22:12:19

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:39:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f0ef267-45da-472b-b59b-927ead416887'	System	14 Aug 2020 16:39:52
User entered 'Yes (Y)'	System	14 Aug 2020 16:39:52

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:39:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f0ef267-45da-472b-b59b-927ead416887'	System	14 Aug 2020 16:39:52
User entered '97.1'	System	14 Aug 2020 16:39:52

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:39:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f0ef267-45da-472b-b59b-927ead416887'	System	14 Aug 2020 16:39:52
User entered 'No (N)'	System	14 Aug 2020 16:39:52

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:39:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f0ef267-45da-472b-b59b-927ead416887'	System	14 Aug 2020 16:39:52
User entered '14 Aug 2020 11:39'	System	14 Aug 2020 16:39:52

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 10:50'	System	14 Aug 2020 15:52:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:45:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '3875f301-9549-4e95-adb6-4541ef0bc2a5'	System	15 Aug 2020 13:46:14
User entered 'Yes (Y)'	System	15 Aug 2020 13:46:14

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:45:37', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '3875f301-9549-4e95-adb6-4541ef0bc2a5'	System	15 Aug 2020 13:46:14
User entered '97.2'	System	15 Aug 2020 13:46:14

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '3875f301-9549-4e95-adb6-4541ef0bc2a5'	System	15 Aug 2020 13:46:14
User entered 'No (N)'	System	15 Aug 2020 13:46:14

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '3875f301-9549-4e95-adb6-4541ef0bc2a5'	System	15 Aug 2020 13:46:14
User entered '15 Aug 2020 08:46'	System	15 Aug 2020 13:46:14

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 14:15'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:52:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 2'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:31:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6dba7741-d02e-4a3a-8bcb-d1597428d9b3'	System	16 Aug 2020 02:32:13
User entered 'Yes (Y)'	System	16 Aug 2020 02:32:13

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:31:58', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6dba7741-d02e-4a3a-8bcb-d1597428d9b3'	System	16 Aug 2020 02:32:13
User entered '97.8'	System	16 Aug 2020 02:32:13

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:02', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6dba7741-d02e-4a3a-8bcb-d1597428d9b3'	System	16 Aug 2020 02:32:13
User entered 'No (N)'	System	16 Aug 2020 02:32:13

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6dba7741-d02e-4a3a-8bcb-d1597428d9b3'	System	16 Aug 2020 02:32:13
User entered '15 Aug 2020 21:32'	System	16 Aug 2020 02:32:13

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 3'	System	14 Aug 2020 15:52:25



US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T20:27:29', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7f6cc373-eef4-40f3-85f4-0319fe9de4ff'	System	17 Aug 2020 01:27:49
User entered 'Yes (Y)'	System	17 Aug 2020 01:27:49

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T20:27:36', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7f6cc373-eef4-40f3-85f4-0319fe9de4ff'	System	17 Aug 2020 01:27:49
User entered '97.9'	System	17 Aug 2020 01:27:49

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T20:27:40', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7f6cc373-eef4-40f3-85f4-0319fe9de4ff'	System	17 Aug 2020 01:27:49
User entered 'No (N)'	System	17 Aug 2020 01:27:49

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T20:27:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7f6cc373-eef4-40f3-85f4-0319fe9de4ff'	System	17 Aug 2020 01:27:49
User entered '16 Aug 2020 20:27'	System	17 Aug 2020 01:27:49

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 4'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f8b4e1ba-11e8-431c-8654-d63a03318252'	System	17 Aug 2020 18:24:37
User entered 'Yes (Y)'	System	17 Aug 2020 18:24:37



US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:25', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f8b4e1ba-11e8-431c-8654-d63a03318252'	System	17 Aug 2020 18:24:37
User entered '97.6'	System	17 Aug 2020 18:24:37

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:29', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f8b4e1ba-11e8-431c-8654-d63a03318252'	System	17 Aug 2020 18:24:37
User entered 'No (N)'	System	17 Aug 2020 18:24:37

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f8b4e1ba-11e8-431c-8654-d63a03318252'	System	17 Aug 2020 18:24:37
User entered '17 Aug 2020 14:24'	System	17 Aug 2020 18:24:37

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 5'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0eee58cc-3c5e-44c7-aabb-629e97d3bb70'	System	18 Aug 2020 20:23:31
User entered 'Yes (Y)'	System	18 Aug 2020 20:23:31

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:13', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0eee58cc-3c5e-44c7-aabb-629e97d3bb70'	System	18 Aug 2020 20:23:31
User entered '96.8'	System	18 Aug 2020 20:23:31



US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0eee58cc-3c5e-44c7-aabb-629e97d3bb70'	System	18 Aug 2020 20:23:31
User entered 'No (N)'	System	18 Aug 2020 20:23:31

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0eee58cc-3c5e-44c7-aabb-629e97d3bb70'	System	18 Aug 2020 20:23:31
User entered '18 Aug 2020 16:23'	System	18 Aug 2020 20:23:31

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 6'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:31:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e2bf16c7-c921-4b7d-a9b0-6cb1d54fe096'	System	19 Aug 2020 18:32:12
User entered 'Yes (Y)'	System	19 Aug 2020 18:32:12

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:31:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e2bf16c7-c921-4b7d-a9b0-6cb1d54fe096'	System	19 Aug 2020 18:32:12
User entered '96.5'	System	19 Aug 2020 18:32:12

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:31:51', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e2bf16c7-c921-4b7d-a9b0-6cb1d54fe096'	System	19 Aug 2020 18:32:12
User entered 'No (N)'	System	19 Aug 2020 18:32:12



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e2bf16c7-c921-4b7d-a9b0-6cb1d54fe096'	System	19 Aug 2020 18:32:12
User entered '19 Aug 2020 14:32'	System	19 Aug 2020 18:32:12

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 7'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c1711dd4-5c7b-40b8-ba0a-aa67c2998b60'	System	20 Aug 2020 17:55:25
User entered 'Yes (Y)'	System	20 Aug 2020 17:55:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:16', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c1711dd4-5c7b-40b8-ba0a-aa67c2998b60'	System	20 Aug 2020 17:55:25
User entered '96.5'	System	20 Aug 2020 17:55:25

US3812169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c1711dd4-5c7b-40b8-ba0a-aa67c2998b60'	System	20 Aug 2020 17:55:25
User entered 'No (N)'	System	20 Aug 2020 17:55:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c1711dd4-5c7b-40b8-ba0a-aa67c2998b60'	System	20 Aug 2020 17:55:25
User entered '20 Aug 2020 13:55'	System	20 Aug 2020 17:55:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:39:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '46827cd2-679a-4fe8-a277-c44b87ad5894'	System	14 Aug 2020 16:40:34
User entered 'None (1)'	System	14 Aug 2020 16:40:34

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '46827cd2-679a-4fe8-a277-c44b87ad5894'	System	14 Aug 2020 16:40:34
User entered 'No (N)'	System	14 Aug 2020 16:40:34

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '46827cd2-679a-4fe8-a277-c44b87ad5894'	System	14 Aug 2020 16:40:34
User entered 'No (N)'	System	14 Aug 2020 16:40:34

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:20', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '46827cd2-679a-4fe8-a277-c44b87ad5894'	System	14 Aug 2020 16:40:34
User entered 'None (1)'	System	14 Aug 2020 16:40:34

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '46827cd2-679a-4fe8-a277-c44b87ad5894'	System	14 Aug 2020 16:40:34
User entered '14 Aug 2020 11:40'	System	14 Aug 2020 16:40:34



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 10:50'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'eb21b1b7-94f5-40bd-8b2f-029b14233a4a'	System	15 Aug 2020 13:46:53
User entered 'None (1)'	System	15 Aug 2020 13:46:53

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'eb21b1b7-94f5-40bd-8b2f-029b14233a4a'	System	15 Aug 2020 13:46:53
User entered 'No (N)'	System	15 Aug 2020 13:46:53

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'eb21b1b7-94f5-40bd-8b2f-029b14233a4a'	System	15 Aug 2020 13:46:53
User entered 'No (N)'	System	15 Aug 2020 13:46:53

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:45', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'eb21b1b7-94f5-40bd-8b2f-029b14233a4a'	System	15 Aug 2020 13:46:53
User entered 'None (1)'	System	15 Aug 2020 13:46:53

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:49', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'eb21b1b7-94f5-40bd-8b2f-029b14233a4a'	System	15 Aug 2020 13:46:53
User entered '15 Aug 2020 08:46'	System	15 Aug 2020 13:46:53



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 14:15'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 2'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e980d45-2f29-4b23-bd20-cebe02cbbef9'	System	16 Aug 2020 02:32:43
User entered 'None (1)'	System	16 Aug 2020 02:32:43

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e980d45-2f29-4b23-bd20-cebe02cbbef9'	System	16 Aug 2020 02:32:43
User entered 'No (N)'	System	16 Aug 2020 02:32:43

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e980d45-2f29-4b23-bd20-cebe02cbbef9'	System	16 Aug 2020 02:32:43
User entered 'No (N)'	System	16 Aug 2020 02:32:43

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:36', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e980d45-2f29-4b23-bd20-cebe02cbbef9'	System	16 Aug 2020 02:32:43
User entered 'None (1)'	System	16 Aug 2020 02:32:43

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:40', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e980d45-2f29-4b23-bd20-cebe02cbbef9'	System	16 Aug 2020 02:32:43
User entered '15 Aug 2020 21:32'	System	16 Aug 2020 02:32:43



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 3'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:06:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '64cc8b41-606c-4c24-ab18-10d75a4931b5'	System	16 Aug 2020 19:07:02
User entered 'None (1)'	System	16 Aug 2020 19:07:02

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:06:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '64cc8b41-606c-4c24-ab18-10d75a4931b5'	System	16 Aug 2020 19:07:02
User entered 'No (N)'	System	16 Aug 2020 19:07:02

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:06:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '64cc8b41-606c-4c24-ab18-10d75a4931b5'	System	16 Aug 2020 19:07:02
User entered 'No (N)'	System	16 Aug 2020 19:07:02

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:06:54', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '64cc8b41-606c-4c24-ab18-10d75a4931b5'	System	16 Aug 2020 19:07:02
User entered 'None (1)'	System	16 Aug 2020 19:07:02

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:06:57', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '64cc8b41-606c-4c24-ab18-10d75a4931b5'	System	16 Aug 2020 19:07:02
User entered '16 Aug 2020 14:06'	System	16 Aug 2020 19:07:02



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 4'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:39', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '436b3e69-00e3-4d84-a753-86beecf794a'	System	17 Aug 2020 18:25:11
User entered 'None (1)'	System	17 Aug 2020 18:25:11

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '436b3e69-00e3-4d84-a753-86beecf794a'	System	17 Aug 2020 18:25:11
User entered 'No (N)'	System	17 Aug 2020 18:25:11

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:24:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '436b3e69-00e3-4d84-a753-86beecf794a'	System	17 Aug 2020 18:25:11
User entered 'No (N)'	System	17 Aug 2020 18:25:11

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '436b3e69-00e3-4d84-a753-86beecf794a'	System	17 Aug 2020 18:25:11
User entered 'None (1)'	System	17 Aug 2020 18:25:11

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:08', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '436b3e69-00e3-4d84-a753-86beecf794a'	System	17 Aug 2020 18:25:11
User entered '17 Aug 2020 14:25'	System	17 Aug 2020 18:25:11



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 5'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:31', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'aebe97ee-7917-465b-a6ea-d054eff27385'	System	18 Aug 2020 20:23:52
User entered 'None (1)'	System	18 Aug 2020 20:23:52

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'aeb97ee-7917-465b-a6ea-d054eff27385'	System	18 Aug 2020 20:23:52
User entered 'No (N)'	System	18 Aug 2020 20:23:52

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:42', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'aeb97ee-7917-465b-a6ea-d054eff27385'	System	18 Aug 2020 20:23:52
User entered 'No (N)'	System	18 Aug 2020 20:23:52

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'aebe97ee-7917-465b-a6ea-d054eff27385'	System	18 Aug 2020 20:23:52
User entered 'None (1)'	System	18 Aug 2020 20:23:52

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'aebe97ee-7917-465b-a6ea-d054eff27385'	System	18 Aug 2020 20:23:52
User entered '18 Aug 2020 16:23'	System	18 Aug 2020 20:23:52



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 6'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e30641b-e1e2-4576-9260-cd20f6bc67c6'	System	19 Aug 2020 18:32:42
User entered 'None (1)'	System	19 Aug 2020 18:32:42

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e30641b-e1e2-4576-9260-cd20f6bc67c6'	System	19 Aug 2020 18:32:42
User entered 'No (N)'	System	19 Aug 2020 18:32:42

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e30641b-e1e2-4576-9260-cd20f6bc67c6'	System	19 Aug 2020 18:32:42
User entered 'No (N)'	System	19 Aug 2020 18:32:42

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e30641b-e1e2-4576-9260-cd20f6bc67c6'	System	19 Aug 2020 18:32:42
User entered 'None (1)'	System	19 Aug 2020 18:32:42

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e30641b-e1e2-4576-9260-cd20f6bc67c6'	System	19 Aug 2020 18:32:42
User entered '19 Aug 2020 14:32'	System	19 Aug 2020 18:32:42



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 7'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:27', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5f094a9c-6a67-4a53-82bf-ccae498395f5'	System	20 Aug 2020 17:55:44
User entered 'None (1)'	System	20 Aug 2020 17:55:44

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5f094a9c-6a67-4a53-82bf-ccae498395f5'	System	20 Aug 2020 17:55:44
User entered 'No (N)'	System	20 Aug 2020 17:55:44

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5f094a9c-6a67-4a53-82bf-ccae498395f5'	System	20 Aug 2020 17:55:44
User entered 'No (N)'	System	20 Aug 2020 17:55:44

US3812169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5f094a9c-6a67-4a53-82bf-ccae498395f5'	System	20 Aug 2020 17:55:44
User entered 'None (1)'	System	20 Aug 2020 17:55:44

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5f094a9c-6a67-4a53-82bf-ccae498395f5'	System	20 Aug 2020 17:55:44
User entered '20 Aug 2020 13:55'	System	20 Aug 2020 17:55:44



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:37', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:40:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'None (0)'	System	14 Aug 2020 16:41:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:41:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered 'No (N)'	System	14 Aug 2020 16:41:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-14T11:41:04', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '10dbe9ec-6617-42db-bbfc-83daaa0bb61b'	System	14 Aug 2020 16:41:09
User entered '14 Aug 2020 11:41'	System	14 Aug 2020 16:41:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 10:50'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:46:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20



US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:02', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:08', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'None (0)'	System	15 Aug 2020 13:47:20

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered 'No (N)'	System	15 Aug 2020 13:47:20

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T08:47:18', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb1125ff-4866-42de-9209-86a4ae9ac7e7'	System	15 Aug 2020 13:47:20
User entered '15 Aug 2020 08:47'	System	15 Aug 2020 13:47:20

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Aug 2020 14:15'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:52:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 2'	System	14 Aug 2020 15:52:25

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:47', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:57', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:32:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'None (0)'	System	16 Aug 2020 02:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:33:02', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered 'No (N)'	System	16 Aug 2020 02:33:09



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-15T21:33:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f9ec3f3f-cf5a-459c-9f8b-3b90fa8c7fe0'	System	16 Aug 2020 02:33:09
User entered '15 Aug 2020 21:33'	System	16 Aug 2020 02:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 3'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:13', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:16', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'None (0)'	System	16 Aug 2020 19:07:28

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc'	System	16 Aug 2020 19:07:28
User entered 'No (N)'	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-16T14:07:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd195a3a7-f3d1-44cf-af5a-9eda37dc46bc' User entered '16 Aug 2020 14:07'	System	16 Aug 2020 19:07:28
	System	16 Aug 2020 19:07:28

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 4'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:33', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'None (0)'	System	17 Aug 2020 18:25:54

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered 'No (N)'	System	17 Aug 2020 18:25:54

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-17T14:25:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1908a995-484d-4b9c-aab0-dac7cac5ea56'	System	17 Aug 2020 18:25:54
User entered '17 Aug 2020 14:25'	System	17 Aug 2020 18:25:54

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:52:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 5'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:54', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:56', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:23:58', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:24:01', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:24:02', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'None (0)'	System	18 Aug 2020 20:24:10



US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:24:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered 'No (N)'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-18T16:24:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1ebadf2e-0429-4386-b63a-431e7d39eca4'	System	18 Aug 2020 20:24:10
User entered '18 Aug 2020 16:24'	System	18 Aug 2020 20:24:10

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 6'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:40', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:32:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:33:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'None (0)'	System	19 Aug 2020 18:33:09

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:33:04', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered 'No (N)'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-19T14:33:06', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5604d73b-9b88-4568-9481-b2bb8f01c960'	System	19 Aug 2020 18:33:09
User entered '19 Aug 2020 14:33'	System	19 Aug 2020 18:33:09

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 7'	System	14 Aug 2020 15:52:25



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:53', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:55:57', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'None (0)'	System	20 Aug 2020 17:56:08

US3812169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:56:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered 'No (N)'	System	20 Aug 2020 17:56:08

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7cb85ec8c137622c)', Time: '2020-08-20T13:56:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5a112c8a-307e-4003-a819-fdca29bd6342'	System	20 Aug 2020 17:56:08
User entered '20 Aug 2020 13:56'	System	20 Aug 2020 17:56:08



**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:52:25

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:12:30

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '21 Aug 2020'	Breanna Galibert (b) (4)	25 Aug 2020 22:12:30

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	25 Aug 2020 22:12:30

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	25 Aug 2020 22:12:30

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Angie Kean (b) (4)	29 Aug 2020 16:17:58

**US3812169**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	29 Aug 2020 16:17:58



**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Angie Kean (b) (4)	29 Aug 2020 16:18:18

**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '29 Aug 2020'	Angie Kean (b) (4)	29 Aug 2020 16:18:18

**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	29 Aug 2020 16:18:18

**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Angie Kean (b) (4)	29 Aug 2020 16:18:18

**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 15:26:59

**US3812169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	03 Sep 2020 15:26:59

**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:08:56

**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:08:56



**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:08:56

**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:08:56

**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:28

**US3812169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	11 Sep 2020 22:42:28

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:40

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:40

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:40

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'VISIT2'	System	11 Sep 2020 22:42:40



US3812169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

US3812169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16:35'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '11 Sep 2020 16:35'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '98.6' F	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '83'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'bpm'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '13'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'breaths/min'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '112'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '70'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	15 Sep 2020 16:29:08



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '17:50'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '11 Sep 2020 17:50'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '97.5' F	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '71'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'bpm'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '12'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

US3812169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'breaths/min'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '120'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '82'	Breanna Galibert (b) (4)	15 Sep 2020 16:29:08

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	15 Sep 2020 16:29:08



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	15 Sep 2020 16:27:49

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	15 Sep 2020 16:27:49

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57

US3812169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57

US3812169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '17:15'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 22:42:57

US3812169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'ONCE'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:01

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:01

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '17:05'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:01

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '11 Sep 2020 17:05'	System	15 Sep 2020 16:28:01



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Sep 2020'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '17:07'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '11 Sep 2020 17:07'	System	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	15 Sep 2020 16:28:13



**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered empty.	System	15 Sep 2020 16:28:13

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 21:04:54

**US3812169**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	18 Sep 2020 21:04:54

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '373cb32a-6181-486c-88f3-18b0d9f0e929'	System	11 Sep 2020 22:50:07
User entered 'Yes (Y)'	System	11 Sep 2020 22:50:07

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:39', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '373cb32a-6181-486c-88f3-18b0d9f0e929'	System	11 Sep 2020 22:50:07
User entered '97.5'	System	11 Sep 2020 22:50:07

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '373cb32a-6181-486c-88f3-18b0d9f0e929'	System	11 Sep 2020 22:50:07
User entered 'No (N)'	System	11 Sep 2020 22:50:07

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '373cb32a-6181-486c-88f3-18b0d9f0e929'	System	11 Sep 2020 22:50:07
User entered '11 Sep 2020 17:49'	System	11 Sep 2020 22:50:07



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 17:35'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 20:05'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:00:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '82fc0a08-ef35-42e1-b025-8c9a5df684d0'	System	12 Sep 2020 02:01:12
User entered 'Yes (Y)'	System	12 Sep 2020 02:01:12

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:00:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '82fc0a08-ef35-42e1-b025-8c9a5df684d0'	System	12 Sep 2020 02:01:12
User entered '97.8'	System	12 Sep 2020 02:01:12

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:00:54', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '82fc0a08-ef35-42e1-b025-8c9a5df684d0'	System	12 Sep 2020 02:01:12
User entered 'No (N)'	System	12 Sep 2020 02:01:12

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:00:57', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '82fc0a08-ef35-42e1-b025-8c9a5df684d0'	System	12 Sep 2020 02:01:12
User entered '11 Sep 2020 21:00'	System	12 Sep 2020 02:01:12

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 21:00'	System	11 Sep 2020 22:42:57



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 2'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:24:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7004f960-7043-4913-b151-70c04b448ece'	System	12 Sep 2020 17:25:06
User entered 'Yes (Y)'	System	12 Sep 2020 17:25:06

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:24:56', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7004f960-7043-4913-b151-70c04b448ece'	System	12 Sep 2020 17:25:06
User entered '97.8'	System	12 Sep 2020 17:25:06

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:24:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7004f960-7043-4913-b151-70c04b448ece'	System	12 Sep 2020 17:25:06
User entered 'No (N)'	System	12 Sep 2020 17:25:06

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7004f960-7043-4913-b151-70c04b448ece'	System	12 Sep 2020 17:25:06
User entered '12 Sep 2020 12:25'	System	12 Sep 2020 17:25:06

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:42:57



US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 3'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'afd77c36-d90b-4449-b66c-77a66086865f'	System	13 Sep 2020 18:31:36
User entered 'Yes (Y)'	System	13 Sep 2020 18:31:36

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'afd77c36-d90b-4449-b66c-77a66086865f' User entered '97.5'	System	13 Sep 2020 18:31:36
	System	13 Sep 2020 18:31:36

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:18', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'afd77c36-d90b-4449-b66c-77a66086865f'	System	13 Sep 2020 18:31:36
User entered 'No (N)'	System	13 Sep 2020 18:31:36

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'afd77c36-d90b-4449-b66c-77a66086865f'	System	13 Sep 2020 18:31:36
User entered '13 Sep 2020 13:31'	System	13 Sep 2020 18:31:36

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 4'	System	11 Sep 2020 22:42:57



US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:01', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f71098cc-8998-4155-93f0-aa9cbb96d850'	System	15 Sep 2020 00:17:20
User entered 'Yes (Y)'	System	15 Sep 2020 00:17:20

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f71098cc-8998-4155-93f0-aa9cbb96d850'	System	15 Sep 2020 00:17:20
User entered '97.5'	System	15 Sep 2020 00:17:20

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:14', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f71098cc-8998-4155-93f0-aa9cbb96d850'	System	15 Sep 2020 00:17:20
User entered 'No (N)'	System	15 Sep 2020 00:17:20

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f71098cc-8998-4155-93f0-aa9cbb96d850'	System	15 Sep 2020 00:17:20
User entered '14 Sep 2020 19:17'	System	15 Sep 2020 00:17:20

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 5'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:34:51', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '48e269eb-d7b8-444d-8706-5ccac00a462b'	System	15 Sep 2020 22:35:09
User entered 'Yes (Y)'	System	15 Sep 2020 22:35:09



US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:34:57', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '48e269eb-d7b8-444d-8706-5ccac00a462b'	System	15 Sep 2020 22:35:09
User entered '97.2'	System	15 Sep 2020 22:35:09

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '48e269eb-d7b8-444d-8706-5ccac00a462b'	System	15 Sep 2020 22:35:09
User entered 'No (N)'	System	15 Sep 2020 22:35:09

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:04', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '48e269eb-d7b8-444d-8706-5ccac00a462b'	System	15 Sep 2020 22:35:09
User entered '15 Sep 2020 17:35'	System	15 Sep 2020 22:35:09

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 6'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:36:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '17e0c923-085b-4d91-8888-3196f0e2c218'	System	17 Sep 2020 11:37:02
User entered 'Yes (Y)'	System	17 Sep 2020 11:37:02

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:36:53', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '17e0c923-085b-4d91-8888-3196f0e2c218'	System	17 Sep 2020 11:37:02
User entered '97.0'	System	17 Sep 2020 11:37:02



US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:36:56', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '17e0c923-085b-4d91-8888-3196f0e2c218'	System	17 Sep 2020 11:37:02
User entered 'No (N)'	System	17 Sep 2020 11:37:02

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '17e0c923-085b-4d91-8888-3196f0e2c218'	System	17 Sep 2020 11:37:02
User entered '17 Sep 2020 06:37'	System	17 Sep 2020 11:37:02

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 7'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '36cfec83-e9c1-4835-ad43-f1332996d980'	System	17 Sep 2020 22:36:54
User entered 'Yes (Y)'	System	17 Sep 2020 22:36:54

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:45', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '36cfec83-e9c1-4835-ad43-f1332996d980'	System	17 Sep 2020 22:36:54
User entered '96.4'	System	17 Sep 2020 22:36:54

US3812169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:49', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '36cfec83-e9c1-4835-ad43-f1332996d980'	System	17 Sep 2020 22:36:54
User entered 'No (N)'	System	17 Sep 2020 22:36:54



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '36cfec83-e9c1-4835-ad43-f1332996d980'	System	17 Sep 2020 22:36:54
User entered '17 Sep 2020 17:36'	System	17 Sep 2020 22:36:54

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:53', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '578b6a8f-fea8-4d38-983e-2b0d4994dda1'	System	11 Sep 2020 22:50:27
User entered 'None (1)'	System	11 Sep 2020 22:50:27

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:49:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '578b6a8f-fea8-4d38-983e-2b0d4994dda1'	System	11 Sep 2020 22:50:27
User entered 'No (N)'	System	11 Sep 2020 22:50:27

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '578b6a8f-fea8-4d38-983e-2b0d4994dda1'	System	11 Sep 2020 22:50:27
User entered 'No (N)'	System	11 Sep 2020 22:50:27

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:06', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '578b6a8f-fea8-4d38-983e-2b0d4994dda1'	System	11 Sep 2020 22:50:27
User entered 'None (1)'	System	11 Sep 2020 22:50:27



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:09', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '578b6a8f-fea8-4d38-983e-2b0d4994dda1'	System	11 Sep 2020 22:50:27
User entered '11 Sep 2020 17:50'	System	11 Sep 2020 22:50:27

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 17:35'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 20:05'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:02', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e4288d29-6d92-43b8-8e5f-a343a22ae0a0'	System	12 Sep 2020 02:01:40
User entered 'None (1)'	System	12 Sep 2020 02:01:40

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e4288d29-6d92-43b8-8e5f-a343a22ae0a0'	System	12 Sep 2020 02:01:40
User entered 'No (N)'	System	12 Sep 2020 02:01:40

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e4288d29-6d92-43b8-8e5f-a343a22ae0a0'	System	12 Sep 2020 02:01:40
User entered 'No (N)'	System	12 Sep 2020 02:01:40

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e4288d29-6d92-43b8-8e5f-a343a22ae0a0'	System	12 Sep 2020 02:01:40
User entered 'None (1)'	System	12 Sep 2020 02:01:40



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e4288d29-6d92-43b8-8e5f-a343a22ae0a0'	System	12 Sep 2020 02:01:40
User entered '11 Sep 2020 21:01'	System	12 Sep 2020 02:01:40

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 21:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 2'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2ed65a80-83c9-4708-919b-798b3e6e2149'	System	12 Sep 2020 17:25:19
User entered 'None (1)'	System	12 Sep 2020 17:25:19

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:10', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2ed65a80-83c9-4708-919b-798b3e6e2149'	System	12 Sep 2020 17:25:19
User entered 'No (N)'	System	12 Sep 2020 17:25:19

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:12', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2ed65a80-83c9-4708-919b-798b3e6e2149'	System	12 Sep 2020 17:25:19
User entered 'No (N)'	System	12 Sep 2020 17:25:19

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:14', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2ed65a80-83c9-4708-919b-798b3e6e2149'	System	12 Sep 2020 17:25:19
User entered 'None (1)'	System	12 Sep 2020 17:25:19



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2ed65a80-83c9-4708-919b-798b3e6e2149'	System	12 Sep 2020 17:25:19
User entered '12 Sep 2020 12:25'	System	12 Sep 2020 17:25:19

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 3'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fe3c9864-5a6d-49fd-837a-674305a44d75'	System	13 Sep 2020 18:31:50
User entered 'None (1)'	System	13 Sep 2020 18:31:50

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:29', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fe3c9864-5a6d-49fd-837a-674305a44d75'	System	13 Sep 2020 18:31:50
User entered 'No (N)'	System	13 Sep 2020 18:31:50

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fe3c9864-5a6d-49fd-837a-674305a44d75'	System	13 Sep 2020 18:31:50
User entered 'No (N)'	System	13 Sep 2020 18:31:50

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fe3c9864-5a6d-49fd-837a-674305a44d75'	System	13 Sep 2020 18:31:50
User entered 'None (1)'	System	13 Sep 2020 18:31:50



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:37', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fe3c9864-5a6d-49fd-837a-674305a44d75'	System	13 Sep 2020 18:31:50
User entered '13 Sep 2020 13:31'	System	13 Sep 2020 18:31:50

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 4'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '8c5ad668-ddb3-421c-ac03-f6bbaa6a13c6'	System	15 Sep 2020 00:17:37
User entered 'None (1)'	System	15 Sep 2020 00:17:37

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '8c5ad668-ddb3-421c-ac03-f6bbaa6a13c6'	System	15 Sep 2020 00:17:37
User entered 'No (N)'	System	15 Sep 2020 00:17:37

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:27', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '8c5ad668-ddb3-421c-ac03-f6bbaa6a13c6'	System	15 Sep 2020 00:17:37
User entered 'No (N)'	System	15 Sep 2020 00:17:37

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '8c5ad668-ddb3-421c-ac03-f6bbaa6a13c6'	System	15 Sep 2020 00:17:37
User entered 'None (1)'	System	15 Sep 2020 00:17:37



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:34', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '8c5ad668-ddb3-421c-ac03-f6bbaa6a13c6'	System	15 Sep 2020 00:17:37
User entered '14 Sep 2020 19:17'	System	15 Sep 2020 00:17:37

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 5'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '92f60ffd-de23-4380-b55b-a57ad6f911ea'	System	15 Sep 2020 22:35:22
User entered 'None (1)'	System	15 Sep 2020 22:35:22

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '92f60ffd-de23-4380-b55b-a57ad6f911ea'	System	15 Sep 2020 22:35:22
User entered 'No (N)'	System	15 Sep 2020 22:35:22

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:14', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '92f60ffd-de23-4380-b55b-a57ad6f911ea'	System	15 Sep 2020 22:35:22
User entered 'No (N)'	System	15 Sep 2020 22:35:22

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '92f60ffd-de23-4380-b55b-a57ad6f911ea'	System	15 Sep 2020 22:35:22
User entered 'None (1)'	System	15 Sep 2020 22:35:22



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '92f60ffd-de23-4380-b55b-a57ad6f911ea'	System	15 Sep 2020 22:35:22
User entered '15 Sep 2020 17:35'	System	15 Sep 2020 22:35:22

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 6'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '34c84622-55d1-4938-bfb5-ffc8c09486bb'	System	17 Sep 2020 11:37:20
User entered 'None (1)'	System	17 Sep 2020 11:37:20

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:08', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '34c84622-55d1-4938-bfb5-ffc8c09486bb'	System	17 Sep 2020 11:37:20
User entered 'No (N)'	System	17 Sep 2020 11:37:20

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '34c84622-55d1-4938-bfb5-ffc8c09486bb'	System	17 Sep 2020 11:37:20
User entered 'No (N)'	System	17 Sep 2020 11:37:20

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '34c84622-55d1-4938-bfb5-ffc8c09486bb'	System	17 Sep 2020 11:37:20
User entered 'None (1)'	System	17 Sep 2020 11:37:20



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:18', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '34c84622-55d1-4938-bfb5-ffc8c09486bb'	System	17 Sep 2020 11:37:20
User entered '17 Sep 2020 06:37'	System	17 Sep 2020 11:37:20

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 7'	System	11 Sep 2020 22:42:57

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b83e52b3-4754-48f5-9d24-222fd97532f7'	System	17 Sep 2020 22:37:09
User entered 'None (1)'	System	17 Sep 2020 22:37:09

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:36:58', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b83e52b3-4754-48f5-9d24-222fd97532f7'	System	17 Sep 2020 22:37:09
User entered 'No (N)'	System	17 Sep 2020 22:37:09

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b83e52b3-4754-48f5-9d24-222fd97532f7'	System	17 Sep 2020 22:37:09
User entered 'No (N)'	System	17 Sep 2020 22:37:09

US3812169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b83e52b3-4754-48f5-9d24-222fd97532f7'	System	17 Sep 2020 22:37:09
User entered 'None (1)'	System	17 Sep 2020 22:37:09



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:05', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b83e52b3-4754-48f5-9d24-222fd97532f7'	System	17 Sep 2020 22:37:09
User entered '17 Sep 2020 17:37'	System	17 Sep 2020 22:37:09

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:13', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:18', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:29', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'None (0)'	System	11 Sep 2020 22:50:45

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered 'No (N)'	System	11 Sep 2020 22:50:45

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T17:50:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '4e9089d9-419e-4b6f-bad5-21ca0da7dad1'	System	11 Sep 2020 22:50:45
User entered '11 Sep 2020 17:50'	System	11 Sep 2020 22:50:45

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 17:35'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 20:05'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:42', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:55', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'None (0)'	System	12 Sep 2020 02:02:11

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:01:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered 'No (N)'	System	12 Sep 2020 02:02:11

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-11T21:02:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '99fa7f25-7dba-420e-9a22-c9428ea89e0e'	System	12 Sep 2020 02:02:11
User entered '11 Sep 2020 21:02'	System	12 Sep 2020 02:02:11

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '11 Sep 2020 21:00'	System	11 Sep 2020 22:42:57



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 2'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'None (0)'	System	12 Sep 2020 17:25:46



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered 'No (N)'	System	12 Sep 2020 17:25:46

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-12T12:25:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e86f414e-2b50-4a0f-829d-b214400d6e76'	System	12 Sep 2020 17:25:46
User entered '12 Sep 2020 12:25'	System	12 Sep 2020 17:25:46

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 3'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:42', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:47', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:49', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:51', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:54', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'None (0)'	System	13 Sep 2020 18:32:10

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:56', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered 'No (N)'	System	13 Sep 2020 18:32:10

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-13T13:31:58', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a97d07d7-b3a6-4fc0-9d83-53e905751bb0'	System	13 Sep 2020 18:32:10
User entered '13 Sep 2020 13:31'	System	13 Sep 2020 18:32:10

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 4'	System	11 Sep 2020 22:42:57



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:40', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:45', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'None (0)'	System	15 Sep 2020 00:17:57

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:52', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered 'No (N)'	System	15 Sep 2020 00:17:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-14T19:17:54', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '558dbfb6-95c5-419b-853d-e71e475411c6'	System	15 Sep 2020 00:17:57
User entered '14 Sep 2020 19:17'	System	15 Sep 2020 00:17:57



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 5'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:34', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'None (0)'	System	15 Sep 2020 22:35:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered 'No (N)'	System	15 Sep 2020 22:35:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-15T17:35:41', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'c6aa6979-c3b0-4fa7-871b-8c29924c87b9'	System	15 Sep 2020 22:35:44
User entered '15 Sep 2020 17:35'	System	15 Sep 2020 22:35:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 6'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44



US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:34', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'None (0)'	System	17 Sep 2020 11:37:44

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered 'No (N)'	System	17 Sep 2020 11:37:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T06:37:40', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0f1ba20d-bc71-4408-82cd-d6f2316d8d13'	System	17 Sep 2020 11:37:44
User entered '17 Sep 2020 06:37'	System	17 Sep 2020 11:37:44

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:42:57



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	11 Sep 2020 22:42:57
User entered 'Day 7'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:14', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'None (0)'	System	17 Sep 2020 22:37:32

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:16', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a' User entered 'None (0)'	System	17 Sep 2020 22:37:32
	System	17 Sep 2020 22:37:32

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'None (0)'	System	17 Sep 2020 22:37:32

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'None (0)'	System	17 Sep 2020 22:37:32

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'None (0)'	System	17 Sep 2020 22:37:32

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'None (0)'	System	17 Sep 2020 22:37:32

US3812169

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered 'No (N)'	System	17 Sep 2020 22:37:32



**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-09-17T17:37:29', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '26de95f7-e775-457b-966a-90991ad8d81a'	System	17 Sep 2020 22:37:32
User entered '17 Sep 2020 17:37'	System	17 Sep 2020 22:37:32

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:51:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:42:57

**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 21:05:04

**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '18 Sep 2020'	Karen Knapp (b) (4)	18 Sep 2020 21:05:04

**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Sep 2020 21:05:04

**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	18 Sep 2020 21:05:04

**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 21:05:08



**US3812169**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	18 Sep 2020 21:05:08

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	25 Sep 2020 18:36:24

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '25 Sep 2020'	Karen Knapp (b) (4)	25 Sep 2020 18:36:24

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	25 Sep 2020 18:36:24

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	25 Sep 2020 18:36:24

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	25 Sep 2020 18:36:28

**US3812169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	25 Sep 2020 18:36:28

**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Oct 2020 21:32:39



**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '2 Oct 2020'	Karen Knapp (b) (4)	02 Oct 2020 21:32:39

**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	02 Oct 2020 21:32:39

**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	02 Oct 2020 21:32:39

**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Oct 2020 21:32:44

**US3812169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	02 Oct 2020 21:32:44

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:08

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '12 Oct 2020'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:08

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:08



**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'VISIT3'	System	13 Oct 2020 20:39:08

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '12 Oct 2020'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16:21'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '12 Oct 2020 16:21'	System	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '98.3' F	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26



**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '76'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'bpm'	System	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'breaths/min'	System	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '108'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '72'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:26

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'mmHg'	System	13 Oct 2020 20:39:26



**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:33

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Breanna Galibert (b) (4)	13 Oct 2020 20:39:33

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:43

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '12 Oct 2020'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:43

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16:55'	Breanna Galibert (b) (4)	13 Oct 2020 20:39:43

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered '12 Oct 2020 16:55'	System	13 Oct 2020 20:39:43



**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	31 Oct 2020 15:07:41

**US3812169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	31 Oct 2020 15:07:41

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 64'	System	14 Aug 2020 15:52:25

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

[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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-14T19:17:31', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '282db27b-8f9e-4a56-a452-e63381b1e714'	System	15 Oct 2020 00:17:56
User entered 'No (N)'	System	15 Oct 2020 00:17:56

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

Have you been exposed to someone with 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-14T19:17:35', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '282db27b-8f9e-4a56-a452-e63381b1e714'	System	15 Oct 2020 00:17:56
User entered 'No (N)'	System	15 Oct 2020 00:17:56

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-14T19:17:42', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '282db27b-8f9e-4a56-a452-e63381b1e714' User entered '14 Oct 2020 19:17:42'	System	15 Oct 2020 00:17:56
	System	15 Oct 2020 00:17:56

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 15:52:25



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 71'	System	14 Aug 2020 15:52:25

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-21T19:03:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '18f0dc96-fda5-47ca-ac52-a20edc680b6f'	System	22 Oct 2020 00:03:54
User entered 'No (N)'	System	22 Oct 2020 00:03:54

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

Have you been exposed to someone with 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-21T19:03:33', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '18f0dc96-fda5-47ca-ac52-a20edc680b6f'	System	22 Oct 2020 00:03:54
User entered 'Yes (Y)'	System	22 Oct 2020 00:03:54

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Please 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-21T19:03:39', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '18f0dc96-fda5-47ca-ac52-a20edc680b6f'	System	22 Oct 2020 00:03:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Oct 2020 00:03:54

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-21T19:03:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '18f0dc96-fda5-47ca-ac52-a20edc680b6f' User entered '21 Oct 2020 19:03:43'	System	22 Oct 2020 00:03:54
	System	22 Oct 2020 00:03:54

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 78'	System	14 Aug 2020 15:52:25



US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

[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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-28T19:37:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '00a1014f-d6ff-445f-96ff-b8b18c7d023d'	System	29 Oct 2020 00:37:49
User entered 'No (N)'	System	29 Oct 2020 00:37:49

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

Have you been exposed to someone with 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-28T19:37:44', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '00a1014f-d6ff-445f-96ff-b8b18c7d023d'	System	29 Oct 2020 00:37:49
User entered 'No (N)'	System	29 Oct 2020 00:37:49

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-10-28T19:37:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '00a1014f-d6ff-445f-96ff-b8b18c7d023d' User entered '28 Oct 2020 19:37:48'	System	29 Oct 2020 00:37:49
	System	29 Oct 2020 00:37:49

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 92'	System	14 Aug 2020 15:52:25

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

[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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-11T06:37:36', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'ebe7d821-45c0-4e0e-9308-e7a9c23e736f'	System	11 Nov 2020 12:37:48
User entered 'No (N)'	System	11 Nov 2020 12:37:48

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

Have you been exposed to someone with 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-11T06:37:39', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'ebe7d821-45c0-4e0e-9308-e7a9c23e736f'	System	11 Nov 2020 12:37:48
User entered 'No (N)'	System	11 Nov 2020 12:37:48



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-11T06:37:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'ebe7d821-45c0-4e0e-9308-e7a9c23e736f' User entered '11 Nov 2020 06:37:43'	System	11 Nov 2020 12:37:48
	System	11 Nov 2020 12:37:48

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered 'Day 99'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-18T19:02:04', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '464aa4bb-7e5a-4597-99b1-7cc8e282f141'	System	19 Nov 2020 01:02:16
User entered 'No (N)'	System	19 Nov 2020 01:02:16

US3812169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:31

Have you been exposed to someone with 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)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-18T19:02:08', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '464aa4bb-7e5a-4597-99b1-7cc8e282f141'	System	19 Nov 2020 01:02:16
User entered 'No (N)'	System	19 Nov 2020 01:02:16

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-18T19:02:14', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '464aa4bb-7e5a-4597-99b1-7cc8e282f141'	System	19 Nov 2020 01:02:16
User entered '18 Nov 2020 19:02:14'	System	19 Nov 2020 01:02:16

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 15:52:25



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:49:11
Data entry locked.	System	14 Aug 2020 15:52:25
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 15:52:25

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-11-23T15:32:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e058febf-4f4a-46d4-b4bd-a4983db14375'	System	23 Nov 2020 21:32:53
User entered 'No (N)'	System	23 Nov 2020 21:32:53

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-11-23T15:32:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e058febf-4f4a-46d4-b4bd-a4983db14375'	System	23 Nov 2020 21:32:53
User entered 'No (N)'	System	23 Nov 2020 21:32:53

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-23T15:32:49', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e058febf-4f4a-46d4-b4bd-a4983db14375'	System	23 Nov 2020 21:32:53
User entered '23 Nov 2020 15:32:49'	System	23 Nov 2020 21:32:53

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:20:30



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-11-29T10:11:20', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6136bc10-a34d-4725-b9f8-ec0f3e900139'	System	29 Nov 2020 16:11:32
User entered 'No (N)'	System	29 Nov 2020 16:11:32

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-11-29T10:11:24', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6136bc10-a34d-4725-b9f8-ec0f3e900139'	System	29 Nov 2020 16:11:32
User entered 'No (N)'	System	29 Nov 2020 16:11:32

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-11-29T10:11:30', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '6136bc10-a34d-4725-b9f8-ec0f3e900139'	System	29 Nov 2020 16:11:32
User entered '29 Nov 2020 10:11:30'	System	29 Nov 2020 16:11:32

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-12-06T11:40:31', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '736da6c2-bfb0-4ede-887a-d662fb95d3a3'	System	06 Dec 2020 17:41:11
User entered 'Yes (Y)'	System	06 Dec 2020 17:41:11

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-12-06T11:40:36', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '736da6c2-bfb0-4ede-887a-d662fb95d3a3'	System	06 Dec 2020 17:41:11
User entered 'No (N)'	System	06 Dec 2020 17:41:11



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-06T11:40:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '736da6c2-bfb0-4ede-887a-d662fb95d3a3'	System	06 Dec 2020 17:41:11
User entered 'No (N)'	System	06 Dec 2020 17:41:11

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-06T11:41:04', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '736da6c2-bfb0-4ede-887a-d662fb95d3a3'	System	06 Dec 2020 17:41:11
User entered 'No (N)'	System	06 Dec 2020 17:41:11

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

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**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-06T11:41:07', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '736da6c2-bfb0-4ede-887a-d662fb95d3a3'	System	06 Dec 2020 17:41:11
User entered '06 Dec 2020 11:41:07'	System	06 Dec 2020 17:41:11

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-12-15T10:56:59', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1eb6f069-dc3b-4ed3-b77a-1dfe9cdd29b0'	System	15 Dec 2020 16:57:09
User entered 'No (N)'	System	15 Dec 2020 16:57:09

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-12-15T10:57:03', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1eb6f069-dc3b-4ed3-b77a-1dfe9cdd29b0'	System	15 Dec 2020 16:57:09
User entered 'No (N)'	System	15 Dec 2020 16:57:09



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-15T10:57:06', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '1eb6f069-dc3b-4ed3-b77a-1dfe9cdd29b0'	System	15 Dec 2020 16:57:09
User entered '15 Dec 2020 10:57:06'	System	15 Dec 2020 16:57:09

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-12-20T09:07:32', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ddcc84f-19ae-4ab8-b589-df69afab38e1'	System	20 Dec 2020 15:07:48
User entered 'No (N)'	System	20 Dec 2020 15:07:48

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-12-20T09:07:38', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ddcc84f-19ae-4ab8-b589-df69afab38e1'	System	20 Dec 2020 15:07:48
User entered 'No (N)'	System	20 Dec 2020 15:07:48

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-20T09:07:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ddcc84f-19ae-4ab8-b589-df69afab38e1'	System	20 Dec 2020 15:07:48
User entered '20 Dec 2020 09:07:43'	System	20 Dec 2020 15:07:48

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2020-12-28T21:26:43', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '683d84fa-2d22-4cf6-8266-0e6a011f901b'	System	29 Dec 2020 03:26:52
User entered 'No (N)'	System	29 Dec 2020 03:26:52

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2020-12-28T21:26:46', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '683d84fa-2d22-4cf6-8266-0e6a011f901b'	System	29 Dec 2020 03:26:52
User entered 'No (N)'	System	29 Dec 2020 03:26:52

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2020-12-28T21:26:50', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '683d84fa-2d22-4cf6-8266-0e6a011f901b'	System	29 Dec 2020 03:26:52
User entered '28 Dec 2020 21:26:50'	System	29 Dec 2020 03:26:52

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:20:30



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-01-03T09:52:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc1c5605-1383-496e-86e7-5e5e1351fed0'	System	03 Jan 2021 15:52:21
User entered 'No (N)'	System	03 Jan 2021 15:52:21

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-01-03T09:52:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc1c5605-1383-496e-86e7-5e5e1351fed0'	System	03 Jan 2021 15:52:21
User entered 'No (N)'	System	03 Jan 2021 15:52:21

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-01-03T09:52:19', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc1c5605-1383-496e-86e7-5e5e1351fed0'	System	03 Jan 2021 15:52:21
User entered '03 Jan 2021 09:52:19'	System	03 Jan 2021 15:52:21

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-01-13T12:09:11', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0b96d203-558d-4bdc-8212-944a56287109'	System	13 Jan 2021 18:09:21
User entered 'No (N)'	System	13 Jan 2021 18:09:21

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-01-13T12:09:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0b96d203-558d-4bdc-8212-944a56287109'	System	13 Jan 2021 18:09:21
User entered 'No (N)'	System	13 Jan 2021 18:09:21



**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-01-13T12:09:18', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '0b96d203-558d-4bdc-8212-944a56287109'	System	13 Jan 2021 18:09:21
User entered '13 Jan 2021 12:09:18'	System	13 Jan 2021 18:09:21

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:20:30

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-01-17T10:22:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ffae096-4e2d-4f99-95e1-7b3b11c275ee'	System	17 Jan 2021 16:22:35
User entered 'No (N)'	System	17 Jan 2021 16:22:35

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-01-17T10:22:23', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ffae096-4e2d-4f99-95e1-7b3b11c275ee'	System	17 Jan 2021 16:22:35
User entered 'No (N)'	System	17 Jan 2021 16:22:35

**US3812169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-01-17T10:22:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '9ffae096-4e2d-4f99-95e1-7b3b11c275ee' User entered '17 Jan 2021 10:22:28'	System	17 Jan 2021 16:22:35
	System	17 Jan 2021 16:22:35

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-01-26T23:20:17', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb859fc1-9912-45bf-b50a-147e854b9c7c'	System	27 Jan 2021 05:20:30
User entered 'No (N)'	System	27 Jan 2021 05:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-01-26T23:20:21', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb859fc1-9912-45bf-b50a-147e854b9c7c'	System	27 Jan 2021 05:20:30
User entered 'No (N)'	System	27 Jan 2021 05:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-01-26T23:20:26', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fb859fc1-9912-45bf-b50a-147e854b9c7c'	System	27 Jan 2021 05:20:30
User entered '26 Jan 2021 23:20:26'	System	27 Jan 2021 05:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-01-31T09:16:39', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2cfea038-5816-45ad-8a7c-838541b207e4'	System	31 Jan 2021 15:16:52
User entered 'No (N)'	System	31 Jan 2021 15:16:52

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-01-31T09:16:42', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2cfea038-5816-45ad-8a7c-838541b207e4'	System	31 Jan 2021 15:16:52
User entered 'No (N)'	System	31 Jan 2021 15:16:52

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-01-31T09:16:48', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '2cfea038-5816-45ad-8a7c-838541b207e4'	System	31 Jan 2021 15:16:52
User entered '31 Jan 2021 09:16:48'	System	31 Jan 2021 15:16:52

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-02-09T12:53:08', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e46a7f2e-2e62-4bcf-8e19-5639f000670e'	System	09 Feb 2021 18:53:19
User entered 'No (N)'	System	09 Feb 2021 18:53:19

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-02-09T12:53:12', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e46a7f2e-2e62-4bcf-8e19-5639f000670e'	System	09 Feb 2021 18:53:19
User entered 'No (N)'	System	09 Feb 2021 18:53:19



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-02-09T12:53:15', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e46a7f2e-2e62-4bcf-8e19-5639f000670e'	System	09 Feb 2021 18:53:19
User entered '09 Feb 2021 12:53:15'	System	09 Feb 2021 18:53:19

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-02-17T10:25:28', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '71e7d48c-d6d5-4cbe-a65f-110bc4cfc960'	System	17 Feb 2021 16:25:41
User entered 'No (N)'	System	17 Feb 2021 16:25:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-02-17T10:25:31', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '71e7d48c-d6d5-4cbe-a65f-110bc4cfc960'	System	17 Feb 2021 16:25:41
User entered 'No (N)'	System	17 Feb 2021 16:25:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-02-17T10:25:36', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '71e7d48c-d6d5-4cbe-a65f-110bc4cfc960'	System	17 Feb 2021 16:25:41
User entered '17 Feb 2021 10:25:36'	System	17 Feb 2021 16:25:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-02-22T21:52:54-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e26c2b66-546c-4f61-aadf-c2fd9d04bb23'	System	23 Feb 2021 03:54:17
User entered 'No (N)'	System	23 Feb 2021 03:54:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-02-22T21:52:57-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e26c2b66-546c-4f61-aadf-c2fd9d04bb23'	System	23 Feb 2021 03:54:17
User entered 'No (N)'	System	23 Feb 2021 03:54:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-02-22T21:53:03-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'e26c2b66-546c-4f61-aadf-c2fd9d04bb23'	System	23 Feb 2021 03:54:17
User entered '22 Feb 2021 21:53:03'	System	23 Feb 2021 03:54:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-03-03T11:06:22-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '19aeb46c-b68a-43db-8716-fa7f60d38dd2'	System	03 Mar 2021 17:17:21
User entered 'No (N)'	System	03 Mar 2021 17:17:21

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-03-03T11:06:25-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '19aeb46c-b68a-43db-8716-fa7f60d38dd2'	System	03 Mar 2021 17:17:21
User entered 'No (N)'	System	03 Mar 2021 17:17:21

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-03T11:06:29-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '19aeb46c-b68a-43db-8716-fa7f60d38dd2'	System	03 Mar 2021 17:17:21
User entered '03 Mar 2021 11:06:29'	System	03 Mar 2021 17:17:21

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-03-08T18:36:31-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '239dbff9-197e-407a-aed2-90c45ef2f55e'	System	09 Mar 2021 00:36:44
User entered 'No (N)'	System	09 Mar 2021 00:36:44

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-03-08T18:36:34-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '239dbff9-197e-407a-aed2-90c45ef2f55e'	System	09 Mar 2021 00:36:44
User entered 'No (N)'	System	09 Mar 2021 00:36:44



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-08T18:36:37-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '239dbff9-197e-407a-aed2-90c45ef2f55e'	System	09 Mar 2021 00:36:44
User entered '08 Mar 2021 18:36:37'	System	09 Mar 2021 00:36:44

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-03-17T11:29:05-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc2bf21e-09b4-49f4-be7f-b37c897557f7'	System	17 Mar 2021 16:29:13
User entered 'No (N)'	System	17 Mar 2021 16:29:13

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-03-17T11:29:07-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc2bf21e-09b4-49f4-be7f-b37c897557f7'	System	17 Mar 2021 16:29:13
User entered 'No (N)'	System	17 Mar 2021 16:29:13

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-17T11:29:10-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'fc2bf21e-09b4-49f4-be7f-b37c897557f7'	System	17 Mar 2021 16:29:13
User entered '17 Mar 2021 11:29:10'	System	17 Mar 2021 16:29:13

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-03-21T01:23:08-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f3c35abf-0c75-4736-9b77-eaea9e75c32d'	System	21 Mar 2021 06:23:17
User entered 'No (N)'	System	21 Mar 2021 06:23:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-03-21T01:23:11-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f3c35abf-0c75-4736-9b77-eaea9e75c32d'	System	21 Mar 2021 06:23:17
User entered 'No (N)'	System	21 Mar 2021 06:23:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-21T01:23:14-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'f3c35abf-0c75-4736-9b77-eaea9e75c32d' User entered '21 Mar 2021 01:23:14'	System	21 Mar 2021 06:23:17
	System	21 Mar 2021 06:23:17

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-03-28T10:20:19-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd8a990c7-50a2-4ec9-8bd6-111b65257459'	System	28 Mar 2021 15:20:37
User entered 'No (N)'	System	28 Mar 2021 15:20:37

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-03-28T10:20:24-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd8a990c7-50a2-4ec9-8bd6-111b65257459'	System	28 Mar 2021 15:20:37
User entered 'No (N)'	System	28 Mar 2021 15:20:37

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-28T10:20:31-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'd8a990c7-50a2-4ec9-8bd6-111b65257459'	System	28 Mar 2021 15:20:37
User entered '28 Mar 2021 10:20:31'	System	28 Mar 2021 15:20:37

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-04-04T06:53:56-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b32cbc77-53c8-458b-a9a7-cb9eea3d4aab'	System	04 Apr 2021 11:54:05
User entered 'No (N)'	System	04 Apr 2021 11:54:05

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-04-04T06:53:58-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b32cbc77-53c8-458b-a9a7-cb9eea3d4aab'	System	04 Apr 2021 11:54:05
User entered 'No (N)'	System	04 Apr 2021 11:54:05



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-04-04T06:54:01-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'b32cbc77-53c8-458b-a9a7-cb9eea3d4aab'	System	04 Apr 2021 11:54:05
User entered '04 Apr 2021 06:54:01'	System	04 Apr 2021 11:54:05

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-04-11T00:15:04-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a483e33a-1d2c-4bbc-8999-21b11fb68fa8' User entered 'No (N)'	System	11 Apr 2021 05:15:15
	System	11 Apr 2021 05:15:15

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-04-11T00:15:07-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a483e33a-1d2c-4bbc-8999-21b11fb68fa8'	System	11 Apr 2021 05:15:15
User entered 'No (N)'	System	11 Apr 2021 05:15:15

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-04-11T00:15:10-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'a483e33a-1d2c-4bbc-8999-21b11fb68fa8'	System	11 Apr 2021 05:15:15
User entered '11 Apr 2021 00:15:10'	System	11 Apr 2021 05:15:15

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-04-21T09:27:34-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'bcf90bcc-1b15-4965-ad25-20301624d2c6'	System	21 Apr 2021 14:27:41
User entered 'No (N)'	System	21 Apr 2021 14:27:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-04-21T09:27:36-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'bcf90bcc-1b15-4965-ad25-20301624d2c6'	System	21 Apr 2021 14:27:41
User entered 'No (N)'	System	21 Apr 2021 14:27:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-04-21T09:27:39-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: 'bcf90bcc-1b15-4965-ad25-20301624d2c6'	System	21 Apr 2021 14:27:41
User entered '21 Apr 2021 09:27:39'	System	21 Apr 2021 14:27:41

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[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 (0996f2c4ab3a6772)', Time: '2021-04-25T09:37:27-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5836a7fa-dcc1-4c7f-b159-b1246fab921' User entered 'No (N)'	System	25 Apr 2021 14:37:36
	System	25 Apr 2021 14:37:36

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

Have you been exposed to someone with 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 (0996f2c4ab3a6772)', Time: '2021-04-25T09:37:29-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5836a7fa-dcc1-4c7f-b159-b1246fab921'	System	25 Apr 2021 14:37:36
User entered 'No (N)'	System	25 Apr 2021 14:37:36

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-04-25T09:37:33-05:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '5836a7fa-dcc1-4c7f-b159-b1246fab921'	System	25 Apr 2021 14:37:36
User entered '25 Apr 2021 09:37:33'	System	25 Apr 2021 14:37:36

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:20:30



**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:20:30

**US3812169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:51:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:30
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:20:30

US3812169

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:51:31**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-03T11:06:08-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7b59613b-75cc-4deb-8397-d8782a5fe5fe'	System	03 Mar 2021 17:17:11
User entered 'No (N)'	System	03 Mar 2021 17:17:11

**US3812169**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0996f2c4ab3a6772)', Time: '2021-03-03T11:06:13-06:00', User OID: 'PatientReportedOutcome (US3812169)', ODM File OID: '7b59613b-75cc-4deb-8397-d8782a5fe5fe'	System	03 Mar 2021 17:17:11
User entered '03 Mar 2021 11:06:13'	System	03 Mar 2021 17:17:11

**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Nov 2020 17:05:00

**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '6 Nov 2020'	Karen Knapp (b) (4)	06 Nov 2020 17:05:00



**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	06 Nov 2020 17:05:00

**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	06 Nov 2020 17:05:00

**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Nov 2020 17:05:05

**US3812169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:13
User entered 'I'	System	06 Nov 2020 17:05:05

**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Dec 2020 16:00:18

**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '9 Dec 2020'	Karen Knapp (b) (4)	09 Dec 2020 16:00:18

**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Dec 2020 16:00:18

**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	09 Dec 2020 16:00:18



**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Dec 2020 16:00:22

**US3812169**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User entered 'I'	System	09 Dec 2020 16:00:22

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Jan 2021 22:29:42

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '8 Jan 2021'	Karen Knapp (b) (4)	08 Jan 2021 22:29:42

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	08 Jan 2021 22:29:42

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	08 Jan 2021 22:29:42

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Jan 2021 22:29:47

**US3812169**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User entered 'I'	System	08 Jan 2021 22:29:47



**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Feb 2021 21:11:11

**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '8 Feb 2021'	Karen Knapp (b) (4)	08 Feb 2021 21:11:11

**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	08 Feb 2021 21:11:11

**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	08 Feb 2021 21:11:11

**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Feb 2021 21:11:15

**US3812169**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:54:14
User entered 'I'	System	08 Feb 2021 21:11:15

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:11

US3812169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '08 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:30:20
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:05
User entered '07 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:05
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:11



**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[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 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:11

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'VISIT4'	System	09 Mar 2021 15:10:11

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

US3812169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:30:20
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Apr 2021 16:30:20
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:30:10
User entered '08 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:30:10
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:29:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Apr 2021 16:29:11
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:11
User entered '07 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:11
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:29:05
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '16:23'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered '08 Mar 2021 16:23'	System	13 Apr 2021 16:30:10
User entered '07 Mar 2021 16:23'	System	13 Apr 2021 16:29:11
User entered '08 Mar 2021 16:23'	System	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '98.8' F	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21



**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '76'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'bpm'	System	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '16'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'breaths/min'	System	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '136'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'mmHg'	System	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '82'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:14:21



**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'mmHg'	System	01 Apr 2021 19:14:21

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:14

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:14

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:20

US3812169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:30:25
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		13 Apr 2021 16:30:25
User entered '08 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:30:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:30:20
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:29:18
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		13 Apr 2021 16:29:18
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:18
User entered '07 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:29:18
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Apr 2021 16:29:05
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:20

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '16:35'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:20



**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered '08 Mar 2021 16:35'	System	13 Apr 2021 16:30:25
User entered '07 Mar 2021 16:35'	System	13 Apr 2021 16:29:18
User entered '08 Mar 2021 16:35'	System	09 Mar 2021 15:10:20

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:53

**US3812169**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:00
User entered 'I'	System	09 Mar 2021 15:10:53

**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:09:57

**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '07 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:09:57

**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:09:57

**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered empty.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:09:57

**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 16:10:01



**US3812169**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:10:01

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:58:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:50:35

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:51:31**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:58:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '10:00'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:50:35

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:51:31**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:58:54
User entered '23 Mar 2021 10:00'	System	23 Mar 2021 16:50:35

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:51:31**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:58:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:50:35

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:58:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:50:35

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '18 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18



**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18



US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:56:18

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '19 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24



**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:57:24

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '20 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:21



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '21 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:58:45

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '22 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12



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Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:12

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38



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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98.6' F	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38



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Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:55:48
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	23 Mar 2021 16:59:38
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:55:48
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	23 Mar 2021 16:59:38
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38



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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (6)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:38

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 7 (Day 7)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '24 Mar 2021'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '96'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '97.8' F	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06



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**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:55:48
	(b) (4)	
User entered 'None (None)'	Angie Kean (b) (4)	25 Mar 2021 14:06:06
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	25 Mar 2021 14:06:06



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Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Day 8 (Day 8)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

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**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '25 Mar 2021'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98.6' F	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15



US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15



**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Mild (Mild)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:45:15

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Day 9 (Day 9)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '26 Mar 2021'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41



**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '96'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User entered '%'	System	29 Mar 2021 14:53:41

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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '97.9' F	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41



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Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Mild (Mild)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41



**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'None (None)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:53:41

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:51:31**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09



US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[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)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:09

**US3812169**

**Folder: Covid-19 Assessment 23 Mar 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:51:31**

**COVID-19 Positive (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:08
User entered '0'	System	01 Apr 2021 19:13:09

US3812169

Folder: Covid-19 Assessment 23 Mar 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:51:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:59:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'No (N)'	(b) (4)	
	Karen Knapp (b) (4)	31 Oct 2020 15:07:50
	(b) (4)	

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 3 (Day 3)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30



**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '25 Mar 2021'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 5 (Day 5)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 7 (Day 7)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30



**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 9 (Day 9)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 14 (Day 14)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 21 (Day 21)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30



**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User accepted default value 'Day 28 (Day 28)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:40
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 13:44:30

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:59

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:59

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 16:59:59

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:47
User entered 'SICKD1'	System	23 Mar 2021 16:59:59



**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '10:45'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User entered '23 Mar 2021 10:45'	System	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '67.0' in	Breanna Galibert (b) (4)	23 Mar 2021 17:00:48
DataPoint set to visible.	(b) (4) System	23 Mar 2021 16:59:59

US3812169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '182.3' lb	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48
DataPoint set to visible.	System	23 Mar 2021 16:59:59

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98.6' F	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48



**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '86'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User entered 'bpm'	System	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '14'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User entered 'breaths/min'	System	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '118'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User entered 'mmHg'	System	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '82'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:00:48



**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56
User entered 'mmHg'	System	23 Mar 2021 17:00:48

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:29:56

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:14
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:03:10

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:14
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:03:10

US3812169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:51:31

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:21
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:10:09

**US3812169**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:30:21
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '23 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:10:09

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:28



**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:28

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:28

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Apr 2021 19:13:28

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:13:36

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36



**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:13:36

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:13:36

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:13:36



**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:13:36

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:42

US3812169

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:42

US3812169

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:51:31**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:50

**US3812169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:51:31**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:13:50

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:43:24

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:43:24



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Clinic (Clinic)'	Heather Cherniawski	11 Feb 2021 21:43:24

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 21:43:24

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:07:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:43

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:07:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:43

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Placebo (Placebo)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:43:39



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Placebo (Placebo)'	Heather Cherniawski	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Placebo (Placebo)'	Heather Cherniawski	11 Feb 2021 21:43:39

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '1'	System	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'I'	System	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '67.1' in	Heather Cherniawski	11 Feb 2021 21:46:48

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '187.8' lb	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '29.38735'	System	11 Feb 2021 21:46:48
DataPoint set to visible.	System	11 Feb 2021 21:43:39



US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '67.1' in	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '187.8' lb	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '29.38735'	System	11 Feb 2021 21:46:48
DataPoint set to visible.	System	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14:55'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '11 Feb 2021 14:55'	System	11 Feb 2021 21:46:48



US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '98.1' F	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '80'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'bpm'	System	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '16'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'breaths/min'	System	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '126'	Heather Cherniawski	11 Feb 2021 21:46:48



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '75'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '67.1' in	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '187.8' lb	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:51:31**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '29.38735'	System	11 Feb 2021 21:46:48
DataPoint set to visible.	System	11 Feb 2021 21:43:39

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15:53'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '11 Feb 2021 15:53'	System	11 Feb 2021 21:46:48

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Feb 2021 22:03:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Feb 2021 22:03:44
User entered '97' F reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:03:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 21:46:48
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Oral (Oral)'	Heather Cherniawski	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Heather Cherniawski	11 Feb 2021 21:46:48

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Feb 2021 22:03:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Feb 2021 22:03:44
User entered '89' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:03:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 21:46:48
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'bpm'	System	11 Feb 2021 22:03:44
User entered empty.	System	11 Feb 2021 21:46:48



US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Feb 2021 22:03:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Feb 2021 22:03:44
User entered '16' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:03:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 21:46:48
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'breaths/min'	System	11 Feb 2021 22:03:44
User entered empty.	System	11 Feb 2021 21:46:48

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Feb 2021 22:03:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Feb 2021 22:03:44
User entered '132' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:03:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 21:46:48
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	11 Feb 2021 22:03:44
User entered empty.	System	11 Feb 2021 21:46:48

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Feb 2021 22:03:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Feb 2021 22:03:44
User entered '86' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:03:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 21:46:48
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	11 Feb 2021 22:03:44
User entered empty.	System	11 Feb 2021 21:46:48

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:45:35

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:45:35



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered empty.	Heather Cherniawski (b) (4)	11 Feb 2021 21:45:04

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered empty.	Heather Cherniawski	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mRNA-1273'	System	11 Feb 2021 21:45:04
DataPoint set to visible.	System	11 Feb 2021 21:43:39

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered '15:23'	Heather Cherniawski	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '11 Feb 2021 15:23'	System	11 Feb 2021 21:45:04

US3812169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	11 Feb 2021 21:45:04



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'ONCE'	System	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 21:45:04

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:44:38

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:44:38

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '14:40'	Heather Cherniawski	11 Feb 2021 21:44:38

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '11 Feb 2021 14:40'	System	11 Feb 2021 21:44:38

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Feb 2021 21:44:25

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 21:44:25



**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:51:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered '14:45'	Heather Cherniawski	11 Feb 2021 21:44:25

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:51:31**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '11 Feb 2021 14:45'	System	11 Feb 2021 21:44:25

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 21:44:06

**US3812169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'I'	System	11 Feb 2021 21:44:06

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Feb 2021 21:39:41

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '18 Feb 2021'	Karen Knapp (b) (4)	18 Feb 2021 21:39:41

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Feb 2021 21:39:41

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered empty.	Karen Knapp (b) (4)	18 Feb 2021 21:39:41



**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Feb 2021 21:39:45

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User entered 'I'	System	18 Feb 2021 21:39:45

**US3812169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:13
User entered '1'	System	18 Feb 2021 21:39:45
DataPoint set to visible.	System	18 Feb 2021 21:39:45

**US3812169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:34

**US3812169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:34

**US3812169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:34

**US3812169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'OLD29'	System	09 Mar 2021 15:08:34

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01



**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '16:23'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '08 Mar 2021 16:23'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98.8' F	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '76'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01



**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'bpm'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '16'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'breaths/min'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '136'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '82'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01



**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '17:17'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '08 Mar 2021 17:17'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '98.4' F	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '83'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01



**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'bpm'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '14'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'breaths/min'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '126'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '84'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mmHg'	System	09 Mar 2021 15:10:01

**US3812169**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:44



**US3812169**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:44

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

US3812169

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'mRNA-1273'	System	09 Mar 2021 15:08:58
DataPoint set to visible.	System	18 Feb 2021 21:39:45

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '16:44'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered '08 Mar 2021 16:44'	System	09 Mar 2021 15:08:58



**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'ONCE'	System	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:51:31**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 15:08:58

**US3812169**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:09:02

**US3812169**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'I'	System	09 Mar 2021 15:09:02

**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:52

**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered '15 Mar 2021'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:52

**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:52



**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:51:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered empty.	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:52

**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:56

**US3812169**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:51:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:47
User entered 'I'	System	15 Mar 2021 20:42:56

**US3812169**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:37:39

**US3812169**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '07 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:37:39

**US3812169**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:37:39

**US3812169**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:51:31**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 17:37:39

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55



**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '07 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '13:43'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 13:43'	System	13 Apr 2021 17:38:55

US3812169

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:18:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per sub i' (Site from System).	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:03
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Apr 2021 17:38:55
User entered '96.4' F	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered empty.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '74'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 17:38:55



**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '12'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '136'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '80'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:51:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 17:38:55

**US3812169**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:07

**US3812169**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:51:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered empty.	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:07



**US3812169**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:14

**US3812169**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '07 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:14

**US3812169**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '14:00'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:39:14

**US3812169**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:51:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 14:00'	System	13 Apr 2021 17:39:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:51:31**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Cherniawski	21 Sep 2020 17:25:41
User entered 'No (N)'	(b) (4)	
	Karen Knapp (b) (4)	03 Sep 2020 15:26:44
	(b) (4)	

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07

US3812169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:31:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:31:59
Data point term sent to Coder	System	21 Sep 2020 17:30:47
User entered 'URINARY TRACT INFECTION'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '27 Aug 2020'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User entered empty.	System	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '3 Sep 2020'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User entered empty.	System	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:30:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:30:47
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:47
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:30:33
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33



US3812169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:24:43
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify. ' answered with 'updated per source' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:44:35
User entered '0' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:44:21
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 00:46:01
User entered '1'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '1' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:44:21
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Heather Cherniawski (b) (4)	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User entered '0'	System	21 Sep 2020 17:30:33

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07
User entered 'I'	System	21 Sep 2020 17:30:33



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:07

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:58:28
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:39:57
User entered	System	12 Jan 2021 16:39:52
'USA-US111-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	12 Jan 2021 16:39:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 22:53:50
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:26:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:26:55
Data point term sent to Coder	System	26 Apr 2021 21:29:56
DataPoint Un-verified.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:29:06
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:29:06
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:29:06
User entered 'Multiple FALLs' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:29:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:14:07
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:18:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:18:48
Data point term sent to Coder	System	11 Jan 2021 23:17:34
User entered 'Fall'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:14:20
User entered 'Yes (Y)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:05
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:08
User entered 'No (N)'	Lylv Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 22:53:59
User closed query 'PV Query: Subject reported that she was admitted to hospital for fall on 17 Dec 2020; however, the event start date and hospital admission date were both noted as 21 Dec 2020 in the source doc. Please consider updating the event start date and hospital admission dates in the EDC. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:37:31
Query 'PV Query: Subject reported that she was admitted to hospital for fall on 17 Dec 2020; however, the event start date and hospital admission date were both noted as 21 Dec 2020 in the source doc. Please consider updating the event start date and hospital admission dates in the EDC. If not updating, please clarify.' answered with 'updated.' (Site from Safety).	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:43:28
DataPoint Un-verified.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:42:21
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:42:21
User entered '17 Dec 2020' reason for change: New Information	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:42:21
User opened query 'PV Query: Subject reported that she was admitted to hospital for fall on 17 Dec 2020; however, the event start date and hospital admission date were both noted as 21 Dec 2020 in the source doc. Please consider updating the event start date and hospital admission dates in the EDC. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 01:41:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:12

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Dec 2020'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:13
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:15
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:17
User closed query 'Per DM CLR: Please review and verify the stop date of this AE as it is episodic and unexpected to last for more than 1 day. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:49:48
Query 'Per DM CLR: Please review and verify the stop date of this AE as it is episodic and unexpected to last for more than 1 day. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	22 Feb 2021 21:48:15
User entered '21 Dec 2020' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	22 Feb 2021 21:48:06
User opened query 'Per DM CLR: Please review and verify the stop date of this AE as it is episodic and unexpected to last for more than 1 day. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:25:08
User entered '07 Jan 2021'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:19
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:21
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:23
User entered 'Yes (Y)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:27
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:29
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:42
User closed query 'Per CDM: Site response noted; however, please complete the "Admitted to ICU?" field. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:03:18
Query 'Per CDM: Site response noted; however, please complete the "Admitted to ICU?" field. Thank you.' answered with 'updated' (Site from DM).	Lyly Dang (b) (4) (b) (4)	14 Jan 2021 21:00:19
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 08:27:08
User opened query 'Per CDM: Site response noted; however, please complete the "Admitted to ICU?" field. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:50:18
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospitalization admission and discharge dates are both noted' (Site from System).	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Jan 2021 23:17:06
User entered 'I'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:49
User entered '21 Dec 2020'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:53
User entered '07 Jan 2021'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:56
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	14 Jan 2021 21:00:14
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:58
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:15:59
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:17:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 23:17:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:47
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:17:06
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:17:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 23:17:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:47
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:17:06
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:36:24
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). Signature has been broken.	System lauren clement (b) (4) (b) (4)	26 Apr 2021 16:43:59
User entered '0' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:43:59
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). DataPoint Un-verified.	System (b) (4), (b) (6)	26 Apr 2021 16:42:21 22 Apr 2021 15:27:11
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User entered '1' reason for change: Data Entry Error	System Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:47 11 Jan 2021 23:17:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User entered '0'	System Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06 11 Jan 2021 23:17:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:36:33
User closed query 'Please clarify as it appears subject had a CT Scan performed while in the hospital, per medical records.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 18:36:31
Query 'Please clarify as it appears subject had a CT Scan performed while in the hospital, per medical records.' answered with 'will reflect CT scans in con procedures ' (Site from CRA).	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:44:31
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:42:21
User entered '1' reason for change: New Information	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:42:21
User opened query 'Please clarify as it appears subject had a CT Scan performed while in the hospital, per medical records.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:27:53
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:27:13
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered '0'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User entered empty.	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User closed query 'PV Query: Please consider adding left foot drop to subject's medical history (prior to onset of study) to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:37:48
User closed query 'PV Query: It was reported that right total knee replacement was on 04 Dec 2020 and right total knee arthroplasty was on 24 Dec 2020. Please confirm what date the procedure was performed and consider updating EDC narrative.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:37:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:36:42
Query 'PV Query: Please consider adding left foot drop to subject's medical history (prior to onset of study) to medical history eCRF.' answered with 'ok' (Site from Safety).	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:45:46
Query 'PV Query: It was reported that right total knee replacement was on 04 Dec 2020 and right total knee arthroplasty was on 24 Dec 2020. Please confirm what date the procedure was performed and consider updating EDC narrative.' answered with 'Error, confirmed right TKA was 04DEC2020' (Site from Safety).	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:45:38
DataPoint Un-verified.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:45:14
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:45:14

US3812169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THIS IS A 67 YEAR OLD FEMALE WHO NOTIFIED SITE STAFF ON 12 JAN 2021, THAT SHE WAS ADMITTED TO THE HOSPITAL DUE TO FREQUENT FALLS ON 17DEC2020. SHE REPORTS SYMPTOMS OF LEFT SIDED WEAKNESS AND RIGHT HIP PAIN. SUBJECT HAS A PERTINENT HISTORY OF RIGHT TOTAL KNEE ARTHROPLASTY ON 04DEC2020, LEFT FOOT DROP SINCE 2013, AND LIVES ALONE. SHE HAD 2+ EDEMA UPON PHYSICAL ASSESSMENT TO THE RIGHT CALF. SUBJECT COMPLETED A CT SCAN OF HER HEAD ON 21DEC2020 AND NO HEMORRHAGE WAS FOUND. SHE COMPLETED AN X-RAY OF HER PELVIS AND RIGHT HIP THAT WAS UNREMARKABLE. SUBJECT DID HAVE AN ELEVATED D-DIMER 3.34. SUBJECT COMPLETED A RIGHT LOWER EXTREMITY ULTRASOUND THAT CONFIRMED NO DVT. SHE COMPLETED A CT OF THE PELVIS ON 22DEC2020 AND THAT WAS UNREMARKABLE. A URINALYSIS WAS OBTAINED AND POSITIVE FOR NITRITES AND 3+ LEUKOCYTES. URINE CULTURE WAS POSITIVE FOR E. COLI. SHE WAS DISCHARGED WITH INSTRUCTIONS TO TAKE MACROBID 100MG TWICE A DAY. DUE TO LIVING ALONE AND RECENT KNEE REPLACEMENT, SHE WAS DISCHARGED TO A REHABILITATION FACILITY. RECORDS DO NOT INDICATE ANY COVID-19 TESTING WAS PERFORMED.' reason for change: New Information	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:45:14
User opened query 'PV Query: Please consider adding left foot drop to subject's medical history (prior to onset of study) to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 01:41:14
User opened query 'PV Query: It was reported that right total knee replacement was on 04 Dec 2020 and right total knee arthroplasty was on 24 Dec 2020. Please confirm what date the procedure was performed and consider updating EDC narrative.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 01:40:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:36:56
User closed query 'Please add to narrative, per progress note details, when and how subject notified site, etc, as site appears to have been notified post-24 hours after SAE occurred, however site did report within 24 hours of being notified by subject. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:36:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'PV Query: Please assess if additional reason(s) for the falls were determined during the duration of the hospitalization. If so please consider reporting as a AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:23:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:23:12
User closed 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)	14 Apr 2021 14:23:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:23:06
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'updated narrative' (Site from Safety).	Angie Kean (b) (4) (b) (4)	13 Apr 2021 15:05:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This is a 67 year old female who notified site staff on 12 JAN 2021, that she was admitted to the hospital due to frequent falls on 17DEC2020. She reports symptoms of left sided weakness and right hip pain. Subject has a pertinent history of right total knee arthroplasty on 24DEC2020, left foot drop since 2013, and lives alone. She had 2+ edema upon physical assessment to the right calf. Subject completed a CT scan of her head on 21DEC2020 and no hemorrhage was found. She completed an x-ray of her pelvis and right hip that was unremarkable. Subject did have an elevated D-Dimer 3.34. Subject completed a right lower extremity ultrasound that confirmed no DVT. She completed a CT of the pelvis on 22DEC2020 and that was unremarkable. A urinalysis was obtained and positive for nitrites and 3+ leukocytes. Urine culture was positive for E. Coli. She was discharged with instructions to take Macrobid 100mg twice a day. Due to living alone and recent knee replacement, she was discharged to a rehabilitation facility. Records do not indicate any COVID-19 testing was performed.'	Angie Kean (b) (4)	13 Apr 2021 15:05:29
reason for change: New Information Query 'Please add to narrative, per progress note details, when and how subject notified site, etc, as site appears to have been notified post-24 hours after SAE occurred, however site did report within 24 hours of being notified by subject. ' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4)	13 Apr 2021 14:59:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THIS IS A 67 YEAR OLD FEMALE WHO NOTIFIED SITE STAFF ON 12 JAN 2021, THAT SHE WAS ADMITTED TO THE HOSPITAL DUE TO FREQUENT FALLS ON 17DEC2020. SHE REPORTS SYMPTOMS OF LEFT SIDED WEAKNESS AND RIGHT HIP PAIN. SUBJECT HAS A PERTINENT HISTORY OF RIGHT TOTAL KNEE ARTHROPLASTY ON 24DEC2020, LEFT FOOT DROP SINCE 2013, AND LIVES ALONE. SHE HAD 2+ EDEMA UPON PHYSICAL ASSESSMENT TO THE RIGHT CALF. SUBJECT COMPLETED A CT SCAN OF HER HEAD ON 21DEC2020 AND NO HEMORRHAGE WAS FOUND. SHE COMPLETED AN X-RAY OF HER PELVIS AND RIGHT HIP THAT WAS UNREMARKABLE. SUBJECT DID HAVE AN ELEVATED D-DIMER 3.34. SUBJECT COMPLETED A RIGHT LOWER EXTREMITY ULTRASOUND THAT CONFIRMED NO DVT. SHE COMPLETED A CT OF THE PELVIS ON 22DEC2020 AND THAT WAS UNREMARKABLE. A URINALYSIS WAS OBTAINED AND POSITIVE FOR NITRITES AND 3+ LEUKOCYTES. URINE CULTURE WAS POSITIVE FOR E. COLI. SHE WAS DISCHARGED WITH INSTRUCTIONS TO TAKE MACROBID 100MG TWICE A DAY. DUE TO LIVING ALONE AND RECENT KNEE REPLACEMENT, SHE WAS DISCHARGED TO A REHABILITATION FACILITY.' reason for change: New Information	Angie Kean (b) (4) (b) (4)	13 Apr 2021 14:59:00
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'please see updated narrative' (Site from Safety).	Angie Kean (b) (4) (b) (4)	13 Apr 2021 14:57:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'please see updated narrative' (Site from Safety).	Angie Kean (b) (4)	13 Apr 2021 14:57:00
Query 'PV Query: Please assess if additional reason(s) for the falls were determined during the duration of the hospitalization. If so please consider reporting as a AE/SAE.' answered with 'please see updated narrative' (Site from Safety).	Angie Kean (b) (4)	13 Apr 2021 14:56:56
DataPoint Un-verified.	Angie Kean (b) (4)	13 Apr 2021 14:55:21
User entered 'This is a 67 year old female that was admitted to the hospital due to frequent falls on 17DEC2020. She reports symptoms of left sided weakness and right hip pain. Subject has a pertinent history of right total knee arthroplasty on 24DEC2020, left foot drop since 2013, and lives alone. She had 2+ edema upon physical assessment to the right calf. Subject completed a CT scan of her head on 21DEC2020 and no hemorrhage was found. She completed an x-ray of her pelvis and right hip that was unremarkable. Subject did have an elevated D-Dimer 3.34. Subject completed a right lower extremity ultrasound that confirmed no DVT. She completed a CT of the pelvis on 22DEC2020 and that was unremarkable. A urinalysis was obtained and positive for nitrites and 3+ leukocytes. Urine culture was positive for E. Coli. She was discharged with instructions to take Macrobid 100mg twice a day. Due to living alone and recent knee replacement, she was discharged to a rehabilitation facility.' reason for change: New Information	Angie Kean (b) (4)	13 Apr 2021 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:16:08
User opened query 'Please add to narrative, per progress note details, when and how subject notified site, etc, as site appears to have been notified post-24 hours after SAE occurred, however site did report within 24 hours of being notified by subject. ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 21:23:15



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Knee replacement surgery was reported in case narrative. Please add to subject's medical history if confirmed prior to starting IP. If not please explain.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 18:32:06
Query 'PV Query: Knee replacement surgery was reported in case narrative. Please add to subject's medical history if confirmed prior to starting IP. If not please explain.' answered with 'Subject did not have TKA prior to screening. Subject reported bilateral OA of knees, and states she had surgery scheduled since MAR2020, but did not disclose that in screening visit. OA of Right Knee did not get worse, pain was the same and she completed the planned procedure in December, as reflected in concomitant procedures.' (Site from Safety).	lauren clement (b) (4) (b) (4)	08 Mar 2021 21:21:32
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:28:34
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)	19 Jan 2021 17:28:25
User opened query 'PV Query: Knee replacement surgery was reported in case narrative. Please add to subject's medical history if confirmed prior to starting IP. If not please explain.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:28:14
User opened query 'PV Query: Please assess if additional reason(s) for the falls were determined during the duration of the hospitalization. If so please consider reporting as a AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:27:53
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)	19 Jan 2021 17:27:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This subject is a 67-year-old female with a past medical history of bilateral osteoarthritis of the knee and a recent surgical history of right total knee replacement on 04 December 2020. Subject reported to site staff that she experienced right-sided sciatica pain after her surgery, which resulted in her falling three times. The subject was subsequently admitted to the hospital for close observation on 21 December 2020 due to being a "high fall risk." Subject was discharged from the hospital on 07 January 2021. Medical records will be requested.'	Lyly Dang (b) (4) (b) (4)	14 Jan 2021 21:00:14
reason for change: Data Entry Error User entered 'On Jan 11, 2021, Subject was contacted by site to clarify findings noted on D148 safety call. During today's call, the subject reported to site staff that she fell three times after her knee replacement surgery. Subject also disclosed that she was hospitalized from 21 Dec 2020 to 07 Jan 2021 due to being a high fall risk. Subject reported attending rehab after her hospitalization. Medical records will be requested.'	Lyly Dang (b) (4) (b) (4)	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:17:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 21:00:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16

US3812169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: R sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:07:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:07:59
Data point term sent to Coder	System	12 Jan 2021 15:40:48
User entered 'RIGHT SIDED SCIATICA'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '21 Dec 2020'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User entered empty.	System	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '30 Dec 2020'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User entered empty.	System	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User entered '0'	System	12 Jan 2021 15:40:30

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16
User entered 'I'	System	12 Jan 2021 15:40:30



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:16

US3812169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint range of motion decreased, LLT: Joint range of motion decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:26:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:26:54
Data point term sent to Coder	System	09 Mar 2021 15:08:29
User entered 'decreased range of motion right knee (post rtka)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:08:21



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

US3812169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:51:26
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:55:09
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 04:54:06
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 15:08:21

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23

US3812169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:45:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:45:39
Data point term sent to Coder	System	09 Mar 2021 18:44:28
User entered 'URINARY TRACT INFECTION'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '11 Feb 2021'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 13:09:31
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:46:38
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 18:44:06
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User entered empty.	System	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '25 Feb 2021'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 13:09:33
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:46:44
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 18:44:06
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User entered empty.	System	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'I'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User entered '0'	System	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23
User entered 'I'	System	09 Mar 2021 18:44:06

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:46:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:46:49
Data point term sent to Coder	System	23 Mar 2021 17:17:11
User entered 'post operative right knee pain'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '05 Dec 2020' reason for change: New Information	Angie Kean (b) (4) (b) (4)	16 Apr 2021 17:53:49
User entered '09 Dec 2020'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:16:51

US3812169

Folder: Adverse Events

Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
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.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
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.' answered with 'still ongoing as of 26 Mar 2021' (Site from DM).	Any Penly (b) (4) (b) (4)	06 Apr 2021 19:49:50
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.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:29:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

US3812169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #8 and 10 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 08:13:20
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #8 and 10 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'updated AE start date. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	16 Apr 2021 17:54:00
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #8 and 10 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:29:42
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 17:16:51



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 17:16:51

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:37:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:37:33
Data point term sent to Coder	System	01 Apr 2021 19:15:51
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:15:26
User entered 'rhinovirus/enterovirus infection' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	01 Apr 2021 19:15:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:58:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:58:16
Data point term sent to Coder	System	29 Mar 2021 14:56:48
User entered 'nasal congestion'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '18 Mar 2021'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User entered empty.	System	29 Mar 2021 14:56:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:58:54
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '01 Apr 2021' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:58:54
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User entered empty.	System	29 Mar 2021 14:56:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '0'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'I'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	29 Mar 2021 14:56:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:58:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User entered '0'	System	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29
User entered '0'	System	29 Mar 2021 14:56:14

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:59:29

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:14
User entered 'USA-US111-2021-mRNA-1273-P301000005'	(b) (4), (b) (6)	14 Apr 2021 13:19:08

US3812169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 18:27:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 18:27:39
Data point term sent to Coder	System	13 Apr 2021 17:57:36
User entered 'urinary tract infection'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:57:09

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '21 Dec 2020'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:37:50
User closed query 'Please clarify end date per Source query, thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 18:37:49
Query 'Please clarify end date per Source query, thank you!' answered with 'updated' (Site from CRA)	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:55:30
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:55:11
User entered '28 Dec 2020' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:55:11
User opened query 'Please clarify end date per Source query, thank you!' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:26:01
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:25:41
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User entered '09 Jan 2021'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	



**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:57:09

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:00
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		16 Apr 2021 17:55:41
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		16 Apr 2021 17:55:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Apr 2021 17:57:09
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	13 Apr 2021 17:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '21 Dec 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Apr 2021 17:55:41
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '28 Dec 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Apr 2021 17:55:41
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Apr 2021 17:55:41
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'I'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:18:53
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 18:29:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Apr 2021 17:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:57:09

**US3812169**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:57:09



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 17:55:41

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:51:31**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:04:07
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:38:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 20:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:46:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:46:10
Data point term sent to Coder	System	17 Aug 2020 20:29:22
User entered 'ZOLPIDUM'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'INSOMNIA'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '10'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:31:19
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	17 Aug 2020 20:29:20
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	17 Aug 2020 20:29:20
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:29:20

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:29:20

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:52:27
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 Apr 2021 03:52:27
Data point term sent to Coder	System	28 Apr 2021 22:04:31
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:03:46
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 00:06:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 00:06:28
Data point term sent to Coder	System	27 Oct 2020 20:40:30
Data point term sent to Coder	System	27 Oct 2020 20:34:18
Coding entries removed.	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 20:33:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:47:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:47:18
Data point term sent to Coder	System	17 Aug 2020 20:30:22
User entered 'GABAPENTEN'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:30:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:30:48
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:30:48
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:29:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:59
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:03:46
User entered 'RIGHT SIDED UnilateRAL PERIPHERAL (BOTH LIMBS) NEUROPATHY' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:03:46
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:26:29
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED PER SUBJECT PHONE CALL AND UPDATED IN SOURCE' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 20:40:02
User entered 'RIGHT SIDED PERIPHERAL (BOTH LIMBS) NEUROPATHY' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 20:39:49
User entered 'RIGHT SIDED LIMBS NEUROPATHY' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 20:33:30
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:56:26

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User entered 'NEUROPATHY'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '100'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'three times daily (TID)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:31:19
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	17 Aug 2020 20:29:58
User entered 'UN Jun 2020'	Breanna Galibert (b) (4)	17 Aug 2020 20:29:58
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:29:58

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:29:58

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:33:39
Data point term sent to Coder	System	25 Aug 2020 15:33:04
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:32:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:32:35
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	25 Aug 2020 15:32:18
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'entry error' (Site from System).	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:32:18
Data point term sent to Coder	System	25 Aug 2020 15:32:03
User entered 'MYrBETRIq' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:31:37



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	19 Aug 2020 07:41:12
Data point term sent to Coder	System	18 Aug 2020 13:44:22
User entered 'MYBETRIA'	Breanna Galibert (b) (4)	18 Aug 2020 13:43:39
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'OVERACTIVE BLADDER'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '25'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:31:19
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	18 Aug 2020 13:43:39
User entered 'UN Nov 2019'	Breanna Galibert (b) (4)	18 Aug 2020 13:43:39
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 13:43:39



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 13:43:39

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 13:43:39

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:50:40
Data point term sent to Coder	System	27 Oct 2020 16:49:55
Coding entries removed.	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:49:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:25:47
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 10:25:47
Data point term sent to Coder	System	28 Sep 2020 17:47:01
User entered 'macrobid'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:46:27

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:23:27
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'UPDATED AE PER SOURCE' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:49:39
User entered 'URINARY TRACT INFECTION' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:49:25
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:21:19
User entered 'urinary track infection'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:46:27

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '100'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:46:27

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '27 Aug 2020'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '03 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27
	(b) (4)	



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:12
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 02:32:18
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.'	Angie Kean (b) (4)	29 Jan 2021 20:33:36
answered with 'updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	29 Jan 2021 20:33:22
	(b) (4)	

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:14:25
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)	11 Nov 2020 17:24:15
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 'UPDATED AE PER SOURCE' (Site from DM).	Maureen Dempsey (b) (4)	27 Oct 2020 16:49:48
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)	22 Oct 2020 21:21:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 17:46:27

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
User entered '1'	System	28 Sep 2020 17:46:27

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
User entered '1'	System	28 Sep 2020 17:46:27

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:07
User entered '804 (804)'	System	28 Sep 2020 17:46:27

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: BUTALBITAL;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;BUTALBITAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:52:46
Data point term sent to Coder	System	28 Sep 2020 17:48:03
User entered 'butalbital/acetaminophen'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'headaches'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:25:54
User entered '50/300' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:52:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED PER SOURCE' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:52:21
User entered '300/500' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	27 Oct 2020 16:52:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:19:02
User entered '500/300'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'un Jan 2017'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:47:51

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:47:51

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
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) (b) (4)	29 Sep 2020 02:41:50
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 02:41:50
Data point term sent to Coder	System	28 Sep 2020 17:49:07
User entered 'tramadol'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'osteoarthritis bilateral knee'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '50'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'un UNK 2018'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:48:45

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:48:45



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:48:45

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:01:53
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 Apr 2021 04:01:53
Data point term sent to Coder	System	28 Apr 2021 22:36:01
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:28
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:42:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:42:25
Data point term sent to Coder	System	13 Oct 2020 20:41:16
User entered 'influenza vaccine'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:59
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:28
User entered 'Flu PROPHALACTIC' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:28
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'prophalactic'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'dose'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Oct 2020 20:41:04
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '08 Oct 2020'	Breanna Galibert (b) (4)	13 Oct 2020 20:41:04
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '08 Oct 2020'	Breanna Galibert (b) (4)	13 Oct 2020 20:41:04
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 20:41:04



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User entered empty.	System	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User entered empty.	System	13 Oct 2020 20:41:04

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:23
User entered empty.	System	13 Oct 2020 20:41:04

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:56:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:56:33
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:59
Data point term sent to Coder DataPoint Un-verified.	System Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:08:35 28 Apr 2021 22:08:24
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:08:24
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:08:24
User entered 'ASPIRIN' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:08:24
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:19:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:19:02

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:20:56
Data point term sent to Coder Coding entries removed.	System Angie Kean (b) (4) (b) (4)	23 Feb 2021 21:00:56 23 Feb 2021 21:00:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:20:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:20:48
Data point term sent to Coder User entered 'ASPRIN'	System Heather Cherniawski (b) (4)	14 Dec 2020 17:19:33 14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:16:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Mar 2021 21:44:59
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:45:22
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:51:19
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 21:00:14
User entered 'POST OP PAIN-RIGHT TOTAL KNEE REPLACEMENT' reason for change: New Information	Angie Kean (b) (4) (b) (4)	23 Feb 2021 21:00:09

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:11:52
User entered 'PAIN'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '325'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:40:12
User closed query 'Please clarify if PRN or BID, per medical records and Source query.' (Site from CRA).		26 Apr 2021 18:40:11
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:40
User entered 'other (OTHER)' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:40
Query 'Please clarify if PRN or BID, per medical records and Source query.' answered with 'Subject reported PRN BID' (Site from CRA).	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:22
User opened query 'Please clarify if PRN or BID, per medical records and Source query.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:36:46
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:40:29
DataPoint Un-verified.	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:40
Signature has been broken.	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:40
User entered 'PRN BID' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:00:40
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '05 Dec 2020'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Heather Cherniawski (b) (4)	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	23 Feb 2021 21:00:09
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Dec 2020 17:19:05
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '19 Dec 2020' reason for change: New Information	Angie Kean (b) (4)	23 Feb 2021 21:00:09
	(b) (4)	
User entered empty.	Heather Cherniawski	14 Dec 2020 17:19:05
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:08
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	14 Dec 2020 17:19:05
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User entered empty.	System	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User entered empty.	System	14 Dec 2020 17:19:05

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:19
User entered empty.	System	14 Dec 2020 17:19:05

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:16:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:16:30
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:51:32
Data point term sent to Coder	System	23 Feb 2021 20:58:54
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' answered with 'NO MEDICAL HISTORY TO ADD, NOT WORSENING IN CONDITION USED AS PROPHYLAXIS' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 20:58:49
Coding entries removed.	Angie Kean (b) (4) (b) (4)	23 Feb 2021 20:58:28
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:12:49



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:33:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:33:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNOSIDE [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 17:21:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 17:21:54
Data point term sent to Coder	System	14 Dec 2020 17:20:36
User entered 'SENNA'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 13). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:35:11
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 13). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'Data is correct. Medication was not given for medical history' (Site from DM).	Angie Kean (b) (4) (b) (4)	16 Mar 2021 19:49:43
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 13). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:45:55
User entered 'Yes (Y)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	23 Feb 2021 20:58:28
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'OPIOID INDUCED CONSTIPATION' reason for change: New Information	Angie Kean (b) (4) (b) (4)	23 Feb 2021 20:58:28
User entered 'CONSTIPATION'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '8.6'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '05 Dec 2020'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '09 Dec 2020'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User entered empty.	System	14 Dec 2020 17:20:15



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User entered empty.	System	14 Dec 2020 17:20:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:22
User entered empty.	System	14 Dec 2020 17:20:15

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
Query 'Please clarify if med should remain, as it is unable to located in medical records. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 23:03:13
User opened query 'Please clarify if med should remain, as it is unable to located in medical records. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 22:57:22
User closed query 'Please clarify as Hydrocodone/Acetaminophen is noted in medical records, and unable to locate OXYCODONE/ACETAMINOPHEN. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 22:57:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 20:55:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 20:55:52
Data point term sent to Coder Coding entries removed.	System Lyly Dang (b) (4) (b) (4)	26 Apr 2021 20:55:12 26 Apr 2021 20:54:34
User entered 'Oxycodone/ACETAMINOPHEN' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 20:54:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 19:16:47

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Lyly Dang (b) (4) (b) (4)	26 Apr 2021 19:16:47  26 Apr 2021 19:16:14 26 Apr 2021 19:15:42
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 19:15:42
User entered 'Hydrocodone/ACETAMINOPHEN' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 19:15:42
Query 'Please clarify as Hydrocodone/ Acetaminophen is noted in medical records, and unable to locate OXYCODONE/ACETAMINOPHEN. ' answered with 'MR page 15. It's in there. Thanks.' (Site from CRA).	lauren clement (b) (4) (b) (4)	26 Apr 2021 17:01:50
User opened query 'Please clarify as Hydrocodone/ Acetaminophen is noted in medical records, and unable to locate OXYCODONE/ACETAMINOPHEN. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:39:18
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:34
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:54:38
Data point term sent to Coder	System	16 Mar 2021 19:54:40
Data point term sent to Coder	System	23 Feb 2021 21:00:56
Data point term sent to Coder	System	23 Feb 2021 20:41:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Angie Kean (b) (4)	23 Feb 2021 20:41:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Dec 2020 17:22:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:22:41
Data point term sent to Coder	System	14 Dec 2020 17:21:37
User entered 'OXYCODONE/ACETAMINOPHEN'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:10:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Mar 2021 21:45:09
User entered 'Post-op pain (right total knee replacement)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	16 Mar 2021 19:54:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:30:03
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:51:41
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 21:00:47
User entered 'POST OP PAIN-RIGHT TOTAL KNEE REPLACEMENT' reason for change: New Information	Angie Kean (b) (4) (b) (4)	23 Feb 2021 21:00:42
User entered 'PAIN-RIGHT SCIATICA' reason for change: New Information	Angie Kean (b) (4) (b) (4)	23 Feb 2021 20:41:28

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:12:57
User entered 'PAIN'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '5/325'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '05 Dec 2020'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:05:30
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '21 Dec 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:16:49
DataPoint Un-verified.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 20:54:34
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 20:54:34
User entered '28 Dec 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 20:54:34
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '12 Jan 2021' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:05:30
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
User entered empty.	System	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
User entered empty.	System	14 Dec 2020 17:21:34

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:26
User entered empty.	System	14 Dec 2020 17:21:34

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:59:59
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 Apr 2021 03:59:59
Data point term sent to Coder	System	28 Apr 2021 22:11:36
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:11:14
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS BILATERAL KNEE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:56:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS BILATERAL KNEE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'Per Investigator on 08 MAR 2021 query response to conmed indication, 'Reconciled this with subject today. States given celebrex prior to TKA; that was scheduled and not worsening OA. Reports physician wanted her to take it. Do not report worsening of R OA as an AE. Subject verbalizes pain was the same and never got worse' ' (Site from DM).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:28:18



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS BILATERAL KNEE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:55:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:57:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:57:50
Data point term sent to Coder	System	08 Mar 2021 22:42:34
Coding entries removed.	lauren clement (b) (4) (b) (4)	08 Mar 2021 22:41:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:23:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:23:42
Data point term sent to Coder	System	14 Dec 2020 17:22:38
User entered 'CELEBREX'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:35:59
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:11:14
User entered 'POST OP PAIN RIGHT TOTAL KNEE REPLACEMENT' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:11:14
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:13:25
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Reconciled this with subject today. States given celebrex prior to TKA; that was scheduled and not worsening OA. Reports physician wanted her to take it. Do not report worsening of R OA as an AE. Subject verbalizes pain was the same and never got worse' (Site from DM).	lauren clement (b) (4) (b) (4)	08 Mar 2021 22:41:59
User entered 'Right knee arthritis' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	08 Mar 2021 22:41:52
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:13:03
User entered 'PAIN'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '200'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '05 Dec 2020'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:04:57
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '11 Dec 2020' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Feb 2021 22:04:57
User entered empty.	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User entered empty.	System	14 Dec 2020 17:22:30



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User entered empty.	System	14 Dec 2020 17:22:30

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:29
User entered empty.	System	14 Dec 2020 17:22:30

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:46:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:46:39
Data point term sent to Coder	System	09 Mar 2021 18:45:29
User entered 'NITROFURANTOIN'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:45:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'URINARY TRACT INFECTION'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '100'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'twice daily (BID)'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:31

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:45:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '18 Feb 2021'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	09 Mar 2021 18:45:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '25 Feb 2021'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	09 Mar 2021 18:45:15
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Mar 2021 18:45:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 18:45:15

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 18:45:15

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:16:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:16:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
Data point term sent to Coder	System	06 Apr 2021 19:37:24
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	06 Apr 2021 19:36:29
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated with active ingredients' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:36:29
Data point term sent to Coder	System	06 Apr 2021 19:36:22
User entered 'THERAFLU [acetaminophen, diphenhydramine, phenylephrine]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:36:16
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:03:35
Data point term sent to Coder	System	23 Mar 2021 17:40:03
User entered 'theraflu'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'nasal congestion'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '650/25/10' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:36:16
User entered '325/25/10'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '20 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '20 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:14
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User entered empty.	System	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User entered empty.	System	23 Mar 2021 17:39:14

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:51
User entered empty.	System	23 Mar 2021 17:39:14

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:17:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:17:00
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
Data point term sent to Coder	System	06 Apr 2021 19:37:24
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	06 Apr 2021 19:37:01
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated with active ingredients' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:37:01
User entered 'THERAFLU [ACETAMINOPHEN, DIPHENHYDRAMINE, PHENYLEPHRINE]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:36:49
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:03:36
Data point term sent to Coder	System	23 Mar 2021 17:40:03
User entered 'theraflu'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'nasal congestion'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '650/25/10' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:36:49
User entered '325/25/10'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:39:44
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User entered empty.	System	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User entered empty.	System	23 Mar 2021 17:39:44

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:55
User entered empty.	System	23 Mar 2021 17:39:44



US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: WAL PHED D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
Data point term sent to Coder	System	06 Apr 2021 19:40:37
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	06 Apr 2021 19:40:32
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated with active ingredient' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:32
User entered 'WAL-PHED [PSEUDOEPHEDRINE]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:15
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:39:42
Data point term sent to Coder	System	23 Mar 2021 17:48:25
User entered 'wal-phed'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'nasal congestion'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '120' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:15
User entered '10'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '21 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '21 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:24
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User entered empty.	System	23 Mar 2021 17:47:24



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User entered empty.	System	23 Mar 2021 17:47:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:58
User entered empty.	System	23 Mar 2021 17:47:24

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: WAL PHED D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
Data point term sent to Coder	System	06 Apr 2021 19:41:38
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	06 Apr 2021 19:40:56
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated with active ingredient' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:56
User entered 'WAL-PHED [PSEUDOEPHEDRINE]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:45
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:39:43
Data point term sent to Coder	System	23 Mar 2021 17:48:25
User entered 'wal-phed'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'nasal congestion'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered '120' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	06 Apr 2021 19:40:45
User entered '10'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '23 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:49
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:49
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:49
	(b) (4)	

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:36:06
	(b) (4)	
User entered '23 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 17:47:49
	(b) (4)	



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:36:06
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User entered empty.	System	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User entered empty.	System	23 Mar 2021 17:47:49

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:17:59
User entered empty.	System	23 Mar 2021 17:47:49

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:32
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 22:37:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 22:37:29
Data point term sent to Coder	System	28 Apr 2021 22:37:02
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:36:58
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:36:58
User entered 'Macrobid' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:36:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 17:00:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 17:00:31
Data point term sent to Coder	System	26 Apr 2021 16:58:40

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Nitrofurantoin'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'UTI'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '100'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'mg (mg)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'twice daily (BID)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'Oral (ORAL)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '22 Dec 2020'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '0'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '28 Dec 2020'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:26:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
User entered '2'	System	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
User entered '1'	System	26 Apr 2021 16:57:42

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:08
User entered '804 (804)'	System	26 Apr 2021 16:57:42

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:24:42
Data point term sent to Coder	System	26 Apr 2021 21:23:51
User entered 'Hydrocodone/acetaminophen'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'Post-op pain Right total knee replacement'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '5/325'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'mg (mg)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'as needed (PRN)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

US3812169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'Oral (ORAL)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered empty.	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '28 Dec 2020'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '0'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '12 Jan 2021'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:30:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
User entered empty.	System	26 Apr 2021 21:23:24

**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
User entered empty.	System	26 Apr 2021 21:23:24



**US3812169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:51:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:18:10
User entered empty.	System	26 Apr 2021 21:23:24

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:51:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:04:07
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Lyly Dang (b) (4)	15 Dec 2020 15:35:13
User entered 'No (N)'	(b) (4) Karen Knapp (b) (4)	03 Sep 2020 15:26:37

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 18:50:20
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 16:53:59
User entered '04 Dec 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 16:53:59
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:47
User entered '4 Dec 2020'	Lyly Dang (b) (4) (b) (4)	15 Dec 2020 15:35:39

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User closed query 'Per CDM: RIGHT TOTAL KNEE REPLACEMENT - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:39:56
Query 'Per CDM: RIGHT TOTAL KNEE REPLACEMENT - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	12 Mar 2021 19:56:10
User opened query 'Per CDM: RIGHT TOTAL KNEE REPLACEMENT - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4)	12 Mar 2021 09:51:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered 'Right Total Knee Replacement'	Lyly Dang (b) (4)	15 Dec 2020 15:35:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
User entered 'Medical History (MH)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	16 Mar 2021 19:55:02
Signature has been broken.	Angie Kean (b) (4) (b) (4)	12 Mar 2021 19:56:06
User entered 'Adverse Event (AE)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	12 Mar 2021 19:56:06
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:47
User entered 'Medical History (MH)'	Lyly Dang (b) (4) (b) (4)	15 Dec 2020 15:35:39

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:51:31**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:47
User entered empty.	Lyly Dang (b) (4)	15 Dec 2020 15:35:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:20
	(b) (4)	
User entered '03 Mar 2021' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 16:54:36
	(b) (4)	
User entered '3 Mar 2021'	Angie Kean (b) (4)	29 Mar 2021 14:55:00
	(b) (4)	

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:20
	(b) (4)	
User entered 'scarring debridement'	Angie Kean (b) (4)	29 Mar 2021 14:55:00
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:02
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:59:30
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 18:50:20
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'DECREASED RANGE OF MOTION RIGHT KNEE (POST RTKA) is corresponding AE' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 16:56:46
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:11:12
User entered 'Adverse Event (AE)'	Angie Kean (b) (4) (b) (4)	29 Mar 2021 14:55:00

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:20
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	29 Mar 2021 14:55:00
	(b) (4)	

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered '21 Dec 2020'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:05

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:51:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'CT OF HEAD'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:05

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:05

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:51:31**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:05

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered '21 Dec 2020'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:51

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'ULTRASOUND OF RIGHT LOWER EXTREMITY'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:51



**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:51

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:51:31**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:50:51

US3812169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:51:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:03
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered '22 Dec 2020'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:51:24

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:03
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'CT OF PELVIS'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:51:24

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:03
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:51:24

**US3812169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:51:31**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:03
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:45:47
User entered empty.	lauren clement (b) (4) (b) (4)	26 Apr 2021 16:51:24

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '12/Jan/2021 16:41'	(b) (4) System	12 Jan 2021 16:41:31

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 16:41:31



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (u) (4), (d) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered '15/Jan/2021 07:30'	(b) (4) System	15 Jan 2021 12:30:16

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 13:46:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 12:30:16

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (u) (4), (o) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
User entered '23/Feb/2021 07:46'	(b) (4) System	23 Feb 2021 13:46:48

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:52:18
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 13:46:48

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User entered '09/Mar/2021 13:52'	System	09 Mar 2021 18:52:44

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:55:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 18:52:44

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered '14/Apr/2021 06:19'	System	14 Apr 2021 13:19:51

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:24:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 13:19:51



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (v) (4), (v) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:42:12
User entered '19/Apr/2021 10:43'	System	19 Apr 2021 14:43:07

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:24:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:42:12
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 14:43:07

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 22:52:55
User entered '26/Apr/2021 16:24'	System	26 Apr 2021 20:24:30

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:51:31

**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.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 22:52:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:24:58
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 20:24:30

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'USA-US111-2021-MRNA-1273-P301000005'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Yes (Y)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'No (N)'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'lauren'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Larkin'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered 'clement'	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'Wadsworth'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '711 Old Ballas Rd Suite 105'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered 'St Louis'	System	12 Jan 2021 16:39:52



**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
User entered 'MO'	System	14 Apr 2021 13:19:08

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:35:00
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:19:37
Un-reviewed for Safety.	System	14 Apr 2021 13:19:08
DataPoint Un-verified.	System	14 Apr 2021 13:19:08
Signature has been broken.	System	14 Apr 2021 13:19:08
User entered empty.	System	14 Apr 2021 13:19:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:41:20
User entered '63141'	System	12 Jan 2021 16:39:52

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:09:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
Reviewed for Safety.	(b) (4) (u) (*), (u) (6)	15 Jan 2021 12:30:06
User entered 'US'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:51:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 12:07:06
User entered '7'	System	26 Apr 2021 20:24:30
User entered '6'	System	19 Apr 2021 14:43:07
User entered '5'	System	14 Apr 2021 13:19:51
User entered '4'	System	09 Mar 2021 18:52:44
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 21:58:18
	(b) (4)	
Signature has been broken.	System	23 Feb 2021 13:46:48
User entered '3'	System	23 Feb 2021 13:46:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:57:58
	(b) (4)	
User entered '2'	System	15 Jan 2021 12:30:16
User entered '1'	System	12 Jan 2021 16:41:31

**US3812169**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:51:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:01:48
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered '27/Apr/2021 08:07'	System	27 Apr 2021 12:07:06

US3812169

Folder: SAE USA-US111-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:51:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:01:48
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:34:37
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 12:07:06