

US3312379 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:00:15

All time stamps listed in this document are displayed in GMT

US3312379

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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Participant ID

US3312379

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

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US3312379

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 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 type="radio"/>
	Amendment 3 <input checked="" 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

US3312379

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3312379

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	DEPRESSION
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)	_____

US3312379

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	SLEEP DIFFICULTY
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)	

US3312379

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

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



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	PERNICIOUS ANEMIA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
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 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	EHLERS-DANLOS SYNDROME TYPE III
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	DEVIATED NASAL SEPTUM
Start date (dd MMM yyyy)	UN (b) (6) 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2016
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1992
Start Year (derived)	1992
Stop Month and Year (derived)	MAY 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	DEVIATED SEPTUM REPAIR
Start date (dd MMM yyyy)	UN MAY 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2016
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2016
Start Year (derived)	2016
Stop Month and Year (derived)	MAY 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2019
Start Year (derived)	2019
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 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	TORN RIGHT MENISCUS
Start date (dd MMM yyyy)	UN UNK 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 (14)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	TACHYCARDIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3312379

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

Condition	OVARIAN CYST (UNKNOWN SIDE)
Start date (dd MMM yyyy)	UN 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)	UN 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

US3312379

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:08 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:08
Height ( <i>xxx.x</i> )	70 in
Weight ( <i>xxx.x</i> )	247 lb
BMI ( <i>xxx.x</i> )	35.51491 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Date of assessment (dd MMM yyyy) 28 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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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) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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



US3312379

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 145344

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) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:08 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:08
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:07 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

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

Treatment Date and Time (derived) 28 AUG 2020 16:36

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	15:55 (24 HR)
Collection date and time (derived)	28 AUG 2020 15:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:49	28 AUG 2020 15:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 16:56

PC Close Date & Time

28 AUG 2020 19:26

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**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 97.9 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 20:40

PC Open Date & Time 28 AUG 2020 20:21

PC Close Date & Time 29 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 18:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

30 AUG 2020 20:24

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

31 AUG 2020 18:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	01 SEP 2020 19:49
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	02 SEP 2020 20:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**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

99.1 °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

03 SEP 2020 20:12

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 16:56

PC Close Date & Time

28 AUG 2020 19:26

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**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

28 AUG 2020 20:35

PC Open Date & Time

28 AUG 2020 20:21

PC Close Date & Time

29 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 18:09

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:25

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**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

31 AUG 2020 18:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**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

01 SEP 2020 19:48

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**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

02 SEP 2020 20:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**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

03 SEP 2020 20:12

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**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 ☐

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:07
PC Open Date & Time	28 AUG 2020 16:56
PC Close Date & Time	28 AUG 2020 19:26

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**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 ☐

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:35
PC Open Date & Time	28 AUG 2020 20:21
PC Close Date & Time	29 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:09
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:23
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 18:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:48
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:12
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3312379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

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*

US3312379

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

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*



US3312379

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	13:44 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 13:44
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 15:27
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3312379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3312379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 25 SEP 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 14:56

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

US3312379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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

Collection date (dd MMM yyyy)	25 SEP 2020
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Collection time (00:00-23:59)	14:15 (24 HR)
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Collection date and time (derived)	25 SEP 2020 14:15
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US3312379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	25 SEP 2020 14:12
Nasopharyngeal Swab 2	No		

US3312379

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 25 SEP 2020 15:27

PC Open Date & Time 25 SEP 2020 15:16

PC Close Date & Time 25 SEP 2020 17:46

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	25 SEP 2020 19:41
PC Open Date & Time	25 SEP 2020 18:41
PC Close Date & Time	26 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	26 SEP 2020 17:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 SEP 2020 18:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**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

97.8 °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

28 SEP 2020 18:19

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**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

97.9 °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

29 SEP 2020 18:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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**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

97.9 °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

30 SEP 2020 19:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 21:05

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 15:27

PC Open Date & Time

25 SEP 2020 15:16

PC Close Date & Time

25 SEP 2020 17:46

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 19:41

PC Open Date & Time

25 SEP 2020 18:41

PC Close Date & Time

26 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 17:17

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

58

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

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

Yes ☒

No ☐

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

60

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

25

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 18:19

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

35

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 18:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 21:06

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**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 ☐

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 15:28
PC Open Date & Time	25 SEP 2020 15:16
PC Close Date & Time	25 SEP 2020 17:46

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**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 ☐

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 19:41
PC Open Date & Time	25 SEP 2020 18:41
PC Close Date & Time	26 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:17
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

108 of 3599

EAB) (1725)

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

110 of 3599

EAB) (1725)

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 18:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 18:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

114 of 3599

EAB) (1725)

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 21:06
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:00:15

<b>TIMEPOINT</b>	DAY 8
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	02 OCT 2020 23:34
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3312379

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:00:15

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 23:34
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3312379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:46

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:16
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

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.*

US3312379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

13:24 (24 HR)

Collection date and time (derived)

23 OCT 2020 13:24

US3312379

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:43:47

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	30 OCT 2020 12:32:07
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59



US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 NOV 2020 12:00:43
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 22:34:18
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 NOV 2020 18:27:06
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 09:44:17
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

08 DEC 2020 12:04:15

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

14 DEC 2020 16:43:29

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 09:37:39

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 DEC 2020 08:12:57
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59



US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

03 JAN 2021 07:44:56

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

13 JAN 2021 17:18:12

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 JAN 2021 12:53:18
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

24 JAN 2021 06:56:18

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

02 FEB 2021 12:00:20

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

09 FEB 2021 12:00:22

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

14 FEB 2021 07:50:45

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

21 FEB 2021 09:09:03

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 MAR 2021 12:01:00
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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	09 MAR 2021 16:58:00
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 MAR 2021 07:44:30
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

23 MAR 2021 16:00:02

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

30 MAR 2021 13:30:33

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 05:16:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

11 APR 2021 08:17:03

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

18 APR 2021 07:20:15

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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

25 APR 2021 09:51:04

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐ Yes ☐

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐  
Yes ☐

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐  
Yes ☐

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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 ☐ Yes ☐

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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°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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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"/>

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐  
Yes ☐

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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 ☐

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59
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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**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°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 ☐



**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

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US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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

**US3312379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3312379

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:00:15

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		02 MAR 2021 12:00:35



US3312379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312379

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312379

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

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

Visit date (dd MMM yyyy)	02 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	VISIT4
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US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

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) \_\_\_\_\_

US3312379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

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.*

US3312379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 APR 2021
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	02 APR 2021 10:26

US3312379

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3312379**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

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*

**US3312379**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

Date of Contact	14 SEP 2020
Time of Contact	09:00
Date and Time of Contact (derived)	14 SEP 2020 09:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.8 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 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 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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"/>

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 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 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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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EAB) (1725)

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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



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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

Date of Visit	14 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	14 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

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US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

Date of Contact	27 OCT 2020
Time of Contact	12:39
Date and Time of Contact (derived)	27 OCT 2020 12:39
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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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Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 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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Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.8 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 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 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 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 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	100.5 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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 type="checkbox"/>
Day 10	<input checked="" 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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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"/>

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

Date of Visit 27 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 27 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0



US3312379

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312379

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:28
Height (xxx.x)	70 in
Weight (xxx.x)	246 lb
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3312379

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 SEP 2020

US3312379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	SICKD1

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 13:15
Height (xxx.x)	70 in
Weight (xxx.x)	246 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3312379

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:53:16

Generated On: 09 Jun 2021 17:00:15

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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) \_\_\_\_\_

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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.*

US3312379

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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) \_\_\_\_\_



US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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.*

US3312379

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:53:08

Generated On: 09 Jun 2021 17:00:15

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312379

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

---

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

---

Visit date (dd MMM yyyy)	05 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	UNBLND_DECIDE
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---

US3312379

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Date of updated informed consent (dd MMM yyyy) 05 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☒ Amendment 6 or later ☐

Date of unblinding (dd MMM yyyy) 04 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3312379

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	10:07 (24 HR)
Collection date and time (derived)	05 MAR 2021 10:07

US3312379

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 01:53:56

Generated On: 09 Jun 2021 17:00:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00 - 23:59)	10:06
Collection Date and Time (derived)	05 MAR 2021 10:06

US3312379

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:58:43

Generated On: 09 Jun 2021 17:00:15

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

NECK STRAIN

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)

04 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

15 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

UPPER RESPIRATORY  
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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

GASTROENTERITIS

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

GASTROENTERITIS

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)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

19 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

BRUISING AT INJECTION SITE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

EXACERBATION OF  
BRONCHIECTASIS

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

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 (11)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

UPPER RESPIRATORY  
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)

21 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death ☐ False

Life threatening ☐ False

Requires inpatient or prolongation of existing Hospitalization ☐ False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

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)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

AEID

Adverse event

EXACERBATION OF  
BRONCHIECTASIS

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)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 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

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

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 (19)

Generated On: 09 Jun 2021 17:00:15

AEID	
Adverse event	RIGHT OVARIAN CYST
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)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (20)

Generated On: 09 Jun 2021 17:00:15

AEID	USA-US300-2021-MRNA-1273-P30 1000023
Adverse event	ENDOMETRIOSIS
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)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 APR 2021
Hospital Discharge Date (dd MMM yyyy)	13 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (20)

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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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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28 Y/O WITH HISTORY OF  
OVARIAN CYSTS,  
ENDOMETRIOSIS, AND RECENT  
RIGHT OVARIAN CYSTECTOMY  
(17MAR2021) DEVELOPED  
SEVERE PELVIC PAIN  
REQUIRING HOSPITALIZATION  
DURING WHICH PAIN  
CONTROLLED WITH  
HYDROCODONE/APAP 5/325  
AND IBUPROFEN 800MG.  
AVIANE OCP'S ALSO INITIATED  
DURING HOSPITALIZATION.  
SUBJECT'S PAIN IS IMPROVED  
BUT NOT RESOLVED. SHE  
CONTINUES TO USE  
MEDICATION AND HAS A  
FOLLOW-UP APPOINTMENT  
WITH HER PHYSICIAN IN 2  
WEEKS. WILL FOLLOW AND  
REQUEST MED RECORDS FOR  
THIS SAE, NOT RELATED TO IP,  
NOT RELATED TO COVID  
INFECTION FOLLOW UP  
21APR21 DEVELOPED SEVERE  
PELVIC PAIN REQUIRING  
HOSPITALIZATION DURING  
WHICH PAIN WAS  
CONTROLLED INITIALLY WITH  
WITH IV MORPHINE THEN  
ALTERNATING  
HYDROCODONE/APAP 5/325  
AND TORADOL Q 3 HOURS.  
LOESTRIN WAS REINITIATED  
DURING HOSPITALIZATION, AS  
SUBJECT HAD RECENTLY  
DISCONTINUED IT AS PART OF

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Generated On: 09 Jun 2021 17:00:15

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HER FAMILY PLANNING. LOPERAMIDE WAS GIVEN FOR AN IRRITABLE BOWEL SYNDROME DIARRHEA FLARE UP THAT DID NOT PROLONG HOSPITALIZATION. AN ULTRASOUND SHOWED INCREASED COMPLEXITY AND SIZE OF A RIGHT OVARIAN MASS THAT WAS PROBABLY POST OP RELATED FLUID FROM PREVIOUS CYSTECTOMY; GYNECOLOGY SERVICE WAS NOT CONCERNED FOR TORSION OR ABSCESS. THE CAUSE OF THE PAIN WAS CONSIDERED TO BE ENDOMETRIOSIS. METABOLIC PROFILE, CBC, AND UA WERE NORMAL. SHE WAS DISCHARGED ON HYDROCODONE/APAP AND IBUPROFEN FOR PAIN. ABDOMINAL PAIN AND DIARRHEA PERSIST. SINCE DISCHARGE SHE HAS FOLLOWED UP WITH PCP AND GYNECOLOGY AND IS NOW ALSO USING VAGINAL DIAZEPAM AND DOING PELVIC FLOOR PHYSICAL THERAPY TO CONTROL PAIN. FURTHER WORKUP AND VISIT WITH GASTROENTEROLOGY ARE SCHEDULED FOR EVAL OF DIARRHEA. RIFAXIMIN, WHICH SUBJECT WAS TAKING FOR

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IBS/DIARRHEA SINCE BEFORE  
THIS EVENT, WAS  
DISCONTINUED. WILL  
CONTINUE TO FOLLOW UNTIL  
HER CONDITIONS RETURN TO  
BASELINE.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
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Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

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Admitted to ICU Derived (CSA Programming Field Only)	
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US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

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)

22 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

02 MAR 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

Persistent or significant disability or incapacity

False

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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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



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Folder: Adverse Events

Form: Adverse Events (22)

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AEID	USA-US300-2021-MRNA-1273-P30 1000020
Adverse event	RIGHT OVARIAN CYST
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)	13 MAR 2021
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)	23 MAR 2021
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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (22)

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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	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	

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Folder: Adverse Events

Form: Adverse Events (22)

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28 YEAR OLD WOMAN WITH  
HISTORY OF RIGHT OVARIAN  
CYST DEVELOPED RIGHT  
OVARIAN CYST PAIN ON  
13MAR21 THAT REQUIRED ER  
VISIT. SUBJECT DISCHARGED  
FROM ER 14MAR21 ON  
TYLENOL, IBUPROFEN, AND  
OXYCODONE. SUBJECT  
RETURNED TO ER ON 16MAR21  
WITH POORLY CONTROLLED  
PAIN AND WAS ADMITTED.  
RIGHT OVARIAN CYSTECTOMY  
WITH OVARIAN  
PRESERVATION WAS  
PERFORMED ON 17MAR21.  
SUBJECT IS RECOVERING  
WELL, BUT STILL HAS PAIN.  
SHE IS ABLE TO COMPLETE  
ADL'S WITHOUT ASSISTANCE  
BUT HAS NOT YET RETURNED  
TO WORK. SHE HAS BEEN  
TAKING AVIANE OCP'S,  
TYLENOL, IBUPROFEN, AND  
OXYCODONE FOR PAIN BUT  
DID NOT REQUIRE PAIN MEDS  
TODAY. WILL PROCURE MED  
RECORDS AND WILL FOLLOW.  
BECAUSE PAIN TODAY HAS  
RETURNED TO LEVELS BELOW  
PREVIOUSLY ASSOCIATED  
WITH THIS PROBLEM, WILL  
CLOSE SAE

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:58:48

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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) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication MIRENA

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify DEVICE

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 EVERY 5 YEARS

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) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication SETRALINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC IDEOPATHIC  
BRONCHIECTASIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

THREE TIMES A WEEK

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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 JUL 2016
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication CETRIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (4)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication TRAZODONE

Prophylaxis Yes ☐  
No ☒

Indication SLEEP DIFFICULTY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (6)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 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)	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 (7)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication ELETRIPTAN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication CYANOCOBALMIN

Prophylaxis Yes ☐  
No ☒

Indication PERNICIOUS ANEMIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	UN	UNK 2009
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 checked="" 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 (9)

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Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 NOV 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 checked="" 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) 22 Apr 2021 20:46:41

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Name of Medication HYPERSALINE SOLUTION 7.0%

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC IDEOPATHIC  
BRONCHIETASIS

Dose per administration 1

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

If dose unit is Other, specify NEBULIZER

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication NECK STRAIN

Dose per administration 24

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 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 (14)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication NECK STRAIN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	14 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication NECK STRAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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

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Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication AUGMENTIN AMOXICILLIN  
875MG/POTASSIUM  
CLAVULANATE125MG

Prophylaxis Yes ☐  
No ☒

Indication BRONCHIECTASIS  
EXACERBATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication SEASONAL INFLUENZA  
VACCINATION

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 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)		12 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 (19)

Data signed: (b) (4) 22 Apr 2021 20:46:41

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY  
INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication AUGMENTIN AMOXICILLIN  
875MG/POTASSIUM  
CLAVULANATE125MG

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
BRONCHIECTASIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication HYDROCODONE 5 MG/  
ACETAMINOPHEN 325 MG

Prophylaxis Yes ☐  
No ☒

Indication TORN RIGHT MENISCUS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication NATURE MADE MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT OVARIAN CYST

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 (23)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)		18 JAN 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC IDIOPATHIC  
BRONCHIECTASIS

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 (24)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 FEB 2021	
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 (25)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication CEFPODOXIME

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 (25)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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 (26)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT OVARIAN CYST PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	14 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT OVARIAN CYST PAIN

Dose per administration 400

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 (27)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	14 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT OVARIAN CYST PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	14 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication TACHYCARDIA

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 (29)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)	07 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication AVIANE (LEVONORGESTREL/  
ETHINYL ESTRADIOL)

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

	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)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication ENDOMETRIOSIS

Dose per administration 800

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

508 of 3599

EAB) (1725)

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication ENDOMETRIOSIS

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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US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

Name of Medication LOPAMIDE

Prophylaxis Yes ☐  
No ☒

Indication ENDOMETRIOSIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 20:46:41

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 20:46:42

Generated On: 09 Jun 2021 17:00:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 NOV 2020	RIGHT MENISCUS REPAIR	Medical History	
17 MAR 2021	RIGHT OVARIAN CYSTECTOMY	Adverse Event	
18 JAN 2021	RIGHT OVARIAN CYSTECTOMY	Adverse Event	



US3312379

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:15

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

US3312379

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:15

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 ☐

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 19:58:42

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000020
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 19:58:42

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000020
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/MAR/2021 08:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 19:58:42

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000020
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/APR/2021 10:45
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

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 19:58:42

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000020
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/APR/2021 13:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000023
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000023
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 11:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:58:48

Generated On: 09 Jun 2021 17:00:15

SAEID	USA-US300-2021-MRNA-1273-P301000023
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 15:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312379 (Prod: Johnson County Clin-Trials)

**US3312379**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:00:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'US3312379'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 19:24:45

US3312379

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 07:03:37
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	11 Sep 2020 20:34:00
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:38:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Sep 2020 18:02:46
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 18:02:07
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	28 Aug 2020 21:39:46

**US3312379**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:02:48
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 18:02:07
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 19:24:46

**US3312379**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:02:49
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 18:02:07
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	28 Aug 2020 21:39:46

**US3312379**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'SCRN'	System	28 Aug 2020 21:39:46

US3312379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered (b) (6) 1992'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 19:24:47



**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '27'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'YEARS'	System	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '27'	System	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Female (F)'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

US3312379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Monica Atwood (b) (4)	02 Sep 2020 16:41:43

US3312379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'I'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43



**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

US3312379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

**US3312379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:15**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	02 Sep 2020 16:41:43

US3312379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Aug 2020'	System	28 Aug 2020 21:40:35



**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2020'	System	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Amendment 3 (3)'	(b) (4) Christa Estrada (b) (4) (b) (4)	28 Aug 2020 21:40:35

US3312379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:40:35

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:40:35

US3312379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 19:24:46

**US3312379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:15**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'I'	System	28 Aug 2020 21:41:03



US3312379

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:41:03

US3312379

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:00:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:29:37

US3312379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
Data point term sent to Coder	System	09 Sep 2020 14:31:06
User entered 'depression'	Karol Moore (b) (4)	09 Sep 2020 14:30:27

US3312379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:30:27



**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2010'	System	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2010'	System	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:30:27

**US3312379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:30:27

US3312379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchial conditions NEC, PT: Bronchiectasis, LLT: Bronchiectasis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 15:03:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 15:03:38
Data point term sent to Coder	System	09 Sep 2020 14:32:07
User entered 'chronic ideopathic bronchiectasis'	Karol Moore (b) (4)	09 Sep 2020 14:31:26

US3312379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un Mar 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:26



**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Mar 2014'	System	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2014'	System	09 Sep 2020 14:31:26

US3312379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:26

**US3312379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:26

US3312379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Difficulty sleeping - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
Data point term sent to Coder	System	09 Sep 2020 14:32:08
User entered 'sleep difficulty'	Karol Moore (b) (4)	09 Sep 2020 14:31:42
	(b) (4)	

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:42



**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2016'	System	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2016'	System	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:42

**US3312379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:42



US3312379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
Data point term sent to Coder	System	09 Sep 2020 14:32:10
User entered 'migraine headaches'	Karol Moore (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2005'	System	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2005'	System	09 Sep 2020 14:31:53



**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:53

**US3312379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:31:53

US3312379

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:32:47
Data point term sent to Coder	System	09 Sep 2020 14:32:10
User entered 'vitamin d deficiency'	Karol Moore (b) (4)	09 Sep 2020 14:32:10
	(b) (4)	

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:32:10



**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2014'	System	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2014'	System	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:32:10

**US3312379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:32:10

US3312379

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Pernicious anaemia, LLT: Pernicious anemia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:39:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:39:47
Data point term sent to Coder	System	09 Sep 2020 14:38:25
User entered 'pernicious anemia'	Karol Moore (b) (4)	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2009'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:38:03



**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2009'	System	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2009'	System	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:38:03

**US3312379**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:38:03

US3312379

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Connective tissue disorders congenital, PT: Ehlers-Danlos syndrome, LLT: Ehlers-Danlos syndrome type III - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:42:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:42:39
Data point term sent to Coder	System	09 Sep 2020 14:41:30
User entered 'ehlers-danlos syndrome type iii'	Karol Moore (b) (4)	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:29



**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2015'	System	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2015'	System	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:40:29

**US3312379**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:40:29



US3312379

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:42:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:42:40
Data point term sent to Coder	System	09 Sep 2020 14:41:29
User entered 'cholecystectomy'	Karol Moore (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un Oct 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un Oct 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Oct 2013'	System	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2013'	System	09 Sep 2020 14:40:48



**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Oct 2013'	System	09 Sep 2020 14:40:48

**US3312379**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2013'	System	09 Sep 2020 14:40:48

US3312379

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:43:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:43:43
Data point term sent to Coder	System	09 Sep 2020 14:42:37
User entered 'cholecystitis'	Karol Moore (b) (4)	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un Oct 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:42:30



**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2013'	System	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2013'	System	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Oct 2013'	System	09 Sep 2020 14:42:30

**US3312379**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2013'	System	09 Sep 2020 14:42:30

US3312379

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:48
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 01:03:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 16:02:42
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 16:02:42
Data point term sent to Coder	System	26 Apr 2021 16:01:48
Coding entries removed.	(b) (4), (b) (6)	26 Apr 2021 16:01:47
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:01:47
User entered 'DEVIATED nasal SEPTUM' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:01:47
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:45:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:45:50
Data point term sent to Coder	System	09 Sep 2020 14:44:41
User entered 'deviated septum'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43

US3312379

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un (b) (6) 1992'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43



**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un May 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:43:43

US3312379

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:15

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered (b) (6) 1992'	System	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '1992'	System	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'May 2016'	System	09 Sep 2020 14:43:43

**US3312379**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2016'	System	09 Sep 2020 14:43:43

US3312379

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:45:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:45:50
Data point term sent to Coder	System	09 Sep 2020 14:44:40
User entered 'deviated septum repair'	Karol Moore (b) (4)	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un May 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:44:00



**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un May 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'May 2016'	System	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2016'	System	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'May 2016'	System	09 Sep 2020 14:44:00

**US3312379**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2016'	System	09 Sep 2020 14:44:00



US3312379

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:18:28
Data point term sent to Coder	System	18 Oct 2020 23:17:27
User entered 'seasonal allergies'	Karol Moore (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un Mar 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Mar 2019'	System	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2019'	System	18 Oct 2020 23:17:25



**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	18 Oct 2020 23:17:25

**US3312379**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	18 Oct 2020 23:17:25

US3312379

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:57:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:57:04
Data point term sent to Coder	System	04 Dec 2020 17:55:55
User entered 'torn right meniscus'	(b) (4), (b) (6)	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:54:56



**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2017'	System	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2017'	System	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	04 Dec 2020 17:54:56

**US3312379**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	04 Dec 2020 17:54:56

US3312379

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 15:03:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 15:03:39
Data point term sent to Coder	System	09 Apr 2021 14:54:14
User entered 'TACHYCARDIA'	Monica Atwood (b) (4)	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'UN UNK 2015'	(b) (4) Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	09 Apr 2021 14:54:07



**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2015'	System	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2015'	System	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Apr 2021 14:54:07

**US3312379**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Apr 2021 14:54:07

US3312379

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 11:55:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 11:55:27
Data point term sent to Coder	System	16 Apr 2021 19:22:12
User entered 'OVARIAN CYST (UNKNOWN SIDE)'	Karol Moore (b) (4)	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered 'UN Jan 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:21:58



**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered 'UN Jan 2020'	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2020'	System	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2020'	System	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'Jan 2020'	System	16 Apr 2021 19:21:58

**US3312379**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:00:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '2020'	System	16 Apr 2021 19:21:58



US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15:08'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '28 Aug 2020 15:08'	System	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '70' in	(b) (4)	09 Sep 2020 14:48:43
DataPoint set to visible.	Karol Moore (b) (4)	28 Aug 2020 21:41:03
	(b) (4)	
	System	

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '247' lb	(b) (4) Karol Moore (b) (4)	09 Sep 2020 14:48:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 21:41:03

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '35.51491'	System	09 Sep 2020 14:48:43
DataPoint set to visible.	System	28 Aug 2020 21:41:03

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'kg/m2'	System	09 Sep 2020 14:48:43
DataPoint set to visible.	System	28 Aug 2020 21:41:03



US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'bpm'	System	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'breaths/min'	System	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43



**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:48:43

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	09 Sep 2020 14:48:43

US3312379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54

**US3312379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54

US3312379

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:12

US3312379

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 22:10:53
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 00:59:31
User entered '28 Aug 2020'	Karol Moore (b) (4)	09 Sep 2020 14:49:12
	(b) (4)	

US3312379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User closed query 'Date of visit is 28Aug2020. Please verify date of assessment for childbearing potential and update as needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:49:07
Query 'Date of visit is 28Aug2020. Please verify date of assessment for childbearing potential and update as needed. ' answered with 'updated' (Site from CRA).	Karol Moore (b) (4) (b) (4)	23 Oct 2020 13:44:32
User entered '28 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Oct 2020 13:44:20
User opened query 'Date of visit is 28Aug2020. Please verify date of assessment for childbearing potential and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	27 Sep 2020 16:51:50
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31



US3312379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

**US3312379**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:00:15**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

US3312379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

US3312379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

**US3312379**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:00:15**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

US3312379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:15

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

**US3312379**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:00:15**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:31

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52



**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:49:52

**US3312379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Sep 2020 14:49:52

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18



US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18



US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

**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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18



US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:50:18

US3312379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:41:24

US3312379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:41:24

US3312379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	28 Aug 2020 21:41:24

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'VISIT1'	System	28 Aug 2020 21:41:24



US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:09:15

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '145344'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:09:15

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:09:15

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

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)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	Christa Estrada (b) (4)	28 Aug 2020 21:42:00

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

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)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	Christa Estrada (b) (4)	28 Aug 2020 21:42:00

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4) (b) (4)	28 Aug 2020 21:42:00

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:00:15**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:00

US3312379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:00



**US3312379**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:00:15**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 18:31:55
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:32:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:32:40

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	09 Sep 2020 14:51:30
	(b) (4)	

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30



US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15:08'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered '28 Aug 2020 15:08'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '98.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'bpm'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30



US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'breaths/min'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '114'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'mmHg'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '78'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'mmHg'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30



US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '17:07'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered '28 Aug 2020 17:07'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '98.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '66'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30



US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'bpm'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'breaths/min'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '111'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'mmHg'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '68'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'mmHg'	System	09 Sep 2020 14:51:30

US3312379

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:37



US3312379

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:51:37

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:15:05
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Oct 2020 13:43:45
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Oct 2020 13:43:42
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:57:52
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:53:16

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty; reason for change Data Entry Error	(b) (4) Karol Moore (b) (4)	23 Oct 2020 13:43:42
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4)	09 Sep 2020 14:53:16
	(b) (4)	

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty; reason for change Data Entry Error	(b) (4)	23 Oct 2020 13:43:42
User entered 'Urine (URINE)'	Karol Moore (b) (4)	09 Sep 2020 14:53:16
	(b) (4)	

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty; reason for change Data Entry Error	(b) (4)	23 Oct 2020 13:43:42
User entered 'Negative (NEGATIVE)'	Karol Moore (b) (4)	09 Sep 2020 14:53:16
	(b) (4)	

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty; reason for change Data Entry Error	(b) (4) Karol Moore (b) (4)	23 Oct 2020 13:43:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	09 Sep 2020 14:53:16
	(b) (4)	

US3312379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:53:16

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:53:16



**US3312379**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered empty.	System	09 Sep 2020 14:53:16

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

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)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '16:36'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered '28 Aug 2020 16:36'	System	28 Aug 2020 21:42:59



US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christa Estrada (b) (4)	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'ONCE'	System	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:42:59

US3312379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:08

US3312379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:08

US3312379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15:55'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:08

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered '28 Aug 2020 15:55'	System	09 Sep 2020 14:57:08

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23



US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15:49'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered '28 Aug 2020 15:49'	System	09 Sep 2020 14:57:23

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

US3312379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:23

**US3312379**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered empty.	System	09 Sep 2020 14:57:23



US3312379

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:57:27

US3312379

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'I'	System	09 Sep 2020 14:57:27

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '09dfd7a7-6a9f-4b30-8352-826b541fe753' User entered 'Yes (Y)'	System	28 Aug 2020 22:07:22
	System	28 Aug 2020 22:07:22

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '09dfd7a7-6a9f-4b30-8352-826b541fe753' User entered '98.3'	System	28 Aug 2020 22:07:22
	System	28 Aug 2020 22:07:22

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '09dfd7a7-6a9f-4b30-8352-826b541fe753'	System	28 Aug 2020 22:07:22
User entered 'No (N)'	System	28 Aug 2020 22:07:22

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:20', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '09dfd7a7-6a9f-4b30-8352-826b541fe753' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 22:07:22
	System	28 Aug 2020 22:07:22

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 16:56'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 19:26'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:38:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c' User entered 'Yes (Y)'	System	29 Aug 2020 01:40:05
	System	29 Aug 2020 01:40:05

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:39:49', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c' User entered '97.9'	System	29 Aug 2020 01:40:05
	System	29 Aug 2020 01:40:05

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:39:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c'	System	29 Aug 2020 01:40:05
User entered 'Yes (Y)'	System	29 Aug 2020 01:40:05

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES ' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:39:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES ' (Site from System).	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:28:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Aug 2020 01:40:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:39:55', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c'	System	29 Aug 2020 01:40:05
User entered '1'	System	29 Aug 2020 01:40:05

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:39:55', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c' User entered '0'	System	29 Aug 2020 01:40:05
	System	29 Aug 2020 01:40:05

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:40:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8dbcba59-bb81-4b26-b644-c2b9473e4c8c'	System	29 Aug 2020 01:40:05
User entered '28 Aug 2020 20:40'	System	29 Aug 2020 01:40:05



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 20:21'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 2'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:38:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a555492-c957-4e0b-96c0-b1b132484a93'	System	29 Aug 2020 23:39:45
User entered 'Yes (Y)'	System	29 Aug 2020 23:39:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:39:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a555492-c957-4e0b-96c0-b1b132484a93'	System	29 Aug 2020 23:39:45
User entered '98.6'	System	29 Aug 2020 23:39:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:39:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a555492-c957-4e0b-96c0-b1b132484a93'	System	29 Aug 2020 23:39:45
User entered 'No (N)'	System	29 Aug 2020 23:39:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:39:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a555492-c957-4e0b-96c0-b1b132484a93'	System	29 Aug 2020 23:39:45
User entered '29 Aug 2020 18:39'	System	29 Aug 2020 23:39:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 3'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b9a82eb6-de1c-4ed5-aac1-01294f42a76c' User entered 'Yes (Y)'	System	31 Aug 2020 01:24:45
	System	31 Aug 2020 01:24:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:24:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b9a82eb6-de1c-4ed5-aac1-01294f42a76c' User entered '98.2'	System	31 Aug 2020 01:24:45
	System	31 Aug 2020 01:24:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:24:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b9a82eb6-de1c-4ed5-aac1-01294f42a76c' User entered 'No (N)'	System	31 Aug 2020 01:24:45
	System	31 Aug 2020 01:24:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:24:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b9a82eb6-de1c-4ed5-aac1-01294f42a76c' User entered '30 Aug 2020 20:24'	System	31 Aug 2020 01:24:45
	System	31 Aug 2020 01:24:45

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 4'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:01:48', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '81c1bba4-a663-4da8-88d1-7b988e439111' User entered 'Yes (Y)'	System	31 Aug 2020 23:01:55
	System	31 Aug 2020 23:01:55

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:01:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '81c1bba4-a663-4da8-88d1-7b988e439111' User entered '98.1'	System	31 Aug 2020 23:01:55
	System	31 Aug 2020 23:01:55

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:01:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '81c1bba4-a663-4da8-88d1-7b988e439111'	System	31 Aug 2020 23:01:55
User entered 'No (N)'	System	31 Aug 2020 23:01:55

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:01:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '81c1bba4-a663-4da8-88d1-7b988e439111'	System	31 Aug 2020 23:01:55
User entered '31 Aug 2020 18:01'	System	31 Aug 2020 23:01:55

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 5'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:28', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d' User entered 'Yes (Y)'	System	02 Sep 2020 00:49:10
	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:53', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d' User entered '98.5'	System	02 Sep 2020 00:49:10
	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:55', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d'	System	02 Sep 2020 00:49:10
User entered 'Yes (Y)'	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES ' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:40:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES ' (Site from System).	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:28:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Sep 2020 00:49:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d'	System	02 Sep 2020 00:49:10
User entered '1'	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d' User entered '0'	System	02 Sep 2020 00:49:10
	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:49:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e095fad7-76dd-4cf1-983c-771168543b2d' User entered '01 Sep 2020 19:49'	System	02 Sep 2020 00:49:10
	System	02 Sep 2020 00:49:10

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 6'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6' User entered 'Yes (Y)'	System	03 Sep 2020 01:59:56
	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:48', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6' User entered '98.3'	System	03 Sep 2020 01:59:56
	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6'	System	03 Sep 2020 01:59:56
User entered 'Yes (Y)'	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES ' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:40:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karol Moore (b) (4)	09 Sep 2020 15:28:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6'	System	03 Sep 2020 01:59:56
User entered '1'	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6' User entered '0'	System	03 Sep 2020 01:59:56
	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f01d46ad-8d1c-4dc0-83e3-81e8995066f6' User entered '02 Sep 2020 20:59'	System	03 Sep 2020 01:59:56
	System	03 Sep 2020 01:59:56

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 7'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:11:58', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '38bc40e1-c6ed-4eea-9d22-89ba4e3f13f3'	System	04 Sep 2020 01:12:08
User entered 'Yes (Y)'	System	04 Sep 2020 01:12:08

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '38bc40e1-c6ed-4eea-9d22-89ba4e3f13f3' User entered '99.1'	System	04 Sep 2020 01:12:08
	System	04 Sep 2020 01:12:08

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:02', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '38bc40e1-c6ed-4eea-9d22-89ba4e3f13f3'	System	04 Sep 2020 01:12:08
User entered 'No (N)'	System	04 Sep 2020 01:12:08

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '38bc40e1-c6ed-4eea-9d22-89ba4e3f13f3'	System	04 Sep 2020 01:12:08
User entered '03 Sep 2020 20:12'	System	04 Sep 2020 01:12:08

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:26', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '124c566a-5880-4727-aedf-e32488502ab1' User entered 'None (1)'	System	28 Aug 2020 22:07:40
	System	28 Aug 2020 22:07:40

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:31', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '124c566a-5880-4727-aedf-e32488502ab1' User entered 'No (N)'	System	28 Aug 2020 22:07:40
	System	28 Aug 2020 22:07:40

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '124c566a-5880-4727-aedf-e32488502ab1' User entered 'No (N)'	System	28 Aug 2020 22:07:40
	System	28 Aug 2020 22:07:40

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '124c566a-5880-4727-aedf-e32488502ab1' User entered 'None (1)'	System	28 Aug 2020 22:07:40
	System	28 Aug 2020 22:07:40

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '124c566a-5880-4727-aedf-e32488502ab1' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 22:07:40
	System	28 Aug 2020 22:07:40

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 16:56'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 19:26'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '20163115-77e0-45c9-bbd9-6875a149929c'	System	29 Aug 2020 01:35:44
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:35:44

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '20163115-77e0-45c9-bbd9-6875a149929c' User entered 'No (N)'	System	29 Aug 2020 01:35:44
	System	29 Aug 2020 01:35:44

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '20163115-77e0-45c9-bbd9-6875a149929c'	System	29 Aug 2020 01:35:44
User entered 'No (N)'	System	29 Aug 2020 01:35:44

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '20163115-77e0-45c9-bbd9-6875a149929c'	System	29 Aug 2020 01:35:44
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:35:44

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '20163115-77e0-45c9-bbd9-6875a149929c' User entered '28 Aug 2020 20:35'	System	29 Aug 2020 01:35:44
	System	29 Aug 2020 01:35:44

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 20:21'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 2'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:08', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4f019f2a-b33b-4bdf-8077-bf69e65f37b1' User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 23:09:33
	System	29 Aug 2020 23:09:33

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4f019f2a-b33b-4bdf-8077-bf69e65f37b1' User entered 'No (N)'	System	29 Aug 2020 23:09:33
	System	29 Aug 2020 23:09:33

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4f019f2a-b33b-4bdf-8077-bf69e65f37b1' User entered 'No (N)'	System	29 Aug 2020 23:09:33
	System	29 Aug 2020 23:09:33

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4f019f2a-b33b-4bdf-8077-bf69e65f37b1' User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 23:09:33

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:31', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4f019f2a-b33b-4bdf-8077-bf69e65f37b1' User entered '29 Aug 2020 18:09'	System	29 Aug 2020 23:09:33
	System	29 Aug 2020 23:09:33

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 3'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:24:47', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3df2daf0-cb31-438c-b55b-c37ac477afb0'	System	31 Aug 2020 01:25:12
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 01:25:12

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:24:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3df2daf0-cb31-438c-b55b-c37ac477afb0' User entered 'No (N)'	System	31 Aug 2020 01:25:12
	System	31 Aug 2020 01:25:12

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:25:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3df2daf0-cb31-438c-b55b-c37ac477afb0' User entered 'No (N)'	System	31 Aug 2020 01:25:12
	System	31 Aug 2020 01:25:12

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:25:08', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3df2daf0-cb31-438c-b55b-c37ac477afb0' User entered 'None (1)'	System	31 Aug 2020 01:25:12
	System	31 Aug 2020 01:25:12

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:25:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3df2daf0-cb31-438c-b55b-c37ac477afb0' User entered '30 Aug 2020 20:25'	System	31 Aug 2020 01:25:12
	System	31 Aug 2020 01:25:12

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 4'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'bd9472bb-6027-4155-8b0e-7216654b4a2f'	System	31 Aug 2020 23:02:26
User entered 'None (1)'	System	31 Aug 2020 23:02:26

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'bd9472bb-6027-4155-8b0e-7216654b4a2f' User entered 'No (N)'	System	31 Aug 2020 23:02:26
	System	31 Aug 2020 23:02:26

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'bd9472bb-6027-4155-8b0e-7216654b4a2f' User entered 'No (N)'	System	31 Aug 2020 23:02:26
	System	31 Aug 2020 23:02:26

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:22', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'bd9472bb-6027-4155-8b0e-7216654b4a2f' User entered 'None (1)'	System	31 Aug 2020 23:02:26
	System	31 Aug 2020 23:02:26

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'bd9472bb-6027-4155-8b0e-7216654b4a2f' User entered '31 Aug 2020 18:02'	System	31 Aug 2020 23:02:26
	System	31 Aug 2020 23:02:26

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 5'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:47:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a400642-b933-4641-b73b-09bc7d0e39b0' User entered 'None (1)'	System	02 Sep 2020 00:48:05
	System	02 Sep 2020 00:48:05

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:47:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a400642-b933-4641-b73b-09bc7d0e39b0' User entered 'No (N)'	System	02 Sep 2020 00:48:05
	System	02 Sep 2020 00:48:05

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:47:58', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a400642-b933-4641-b73b-09bc7d0e39b0' User entered 'No (N)'	System	02 Sep 2020 00:48:05
	System	02 Sep 2020 00:48:05

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a400642-b933-4641-b73b-09bc7d0e39b0'	System	02 Sep 2020 00:48:05
User entered 'None (1)'	System	02 Sep 2020 00:48:05

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '4a400642-b933-4641-b73b-09bc7d0e39b0' User entered '01 Sep 2020 19:48'	System	02 Sep 2020 00:48:05
	System	02 Sep 2020 00:48:05

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 6'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3df45c7-d335-48f9-a82d-0dba53c106de' User entered 'None (1)'	System	03 Sep 2020 01:59:23
	System	03 Sep 2020 01:59:23

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3df45c7-d335-48f9-a82d-0dba53c106de' User entered 'No (N)'	System	03 Sep 2020 01:59:23
	System	03 Sep 2020 01:59:23

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3df45c7-d335-48f9-a82d-0dba53c106de' User entered 'No (N)'	System	03 Sep 2020 01:59:23
	System	03 Sep 2020 01:59:23

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3df45c7-d335-48f9-a82d-0dba53c106de' User entered 'None (1)'	System	03 Sep 2020 01:59:23
	System	03 Sep 2020 01:59:23

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3df45c7-d335-48f9-a82d-0dba53c106de' User entered '02 Sep 2020 20:59'	System	03 Sep 2020 01:59:23
	System	03 Sep 2020 01:59:23

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 7'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:08', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3dd5b84-a3ab-4aa6-9a40-7061b9f616e8' User entered 'None (1)'	System	04 Sep 2020 01:12:28
	System	04 Sep 2020 01:12:28

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:11', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3dd5b84-a3ab-4aa6-9a40-7061b9f616e8' User entered 'No (N)'	System	04 Sep 2020 01:12:28
	System	04 Sep 2020 01:12:28

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:21', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3dd5b84-a3ab-4aa6-9a40-7061b9f616e8' User entered 'No (N)'	System	04 Sep 2020 01:12:28
	System	04 Sep 2020 01:12:28

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3dd5b84-a3ab-4aa6-9a40-7061b9f616e8' User entered 'None (1)'	System	04 Sep 2020 01:12:28
	System	04 Sep 2020 01:12:28

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:26', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a3dd5b84-a3ab-4aa6-9a40-7061b9f616e8' User entered '03 Sep 2020 20:12'	System	04 Sep 2020 01:12:28
	System	04 Sep 2020 01:12:28

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:47', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:48', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'None (0)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered 'No (N)'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T17:07:58', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2e753269-0fca-4c4b-8208-9f4fdc39677a' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 22:08:00
	System	28 Aug 2020 22:08:00

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 16:56'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 19:26'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69'	System	29 Aug 2020 01:35:08
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69' User entered 'None (0)'	System	29 Aug 2020 01:35:08
	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69' User entered 'None (0)'	System	29 Aug 2020 01:35:08
	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:55', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69' User entered 'None (0)'	System	29 Aug 2020 01:35:08
	System	29 Aug 2020 01:35:08



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69' User entered 'None (0)'	System	29 Aug 2020 01:35:08
	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:34:59', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69' User entered 'None (0)'	System	29 Aug 2020 01:35:08
	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69'	System	29 Aug 2020 01:35:08
User entered 'No (N)'	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-28T20:35:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9e6b6384-ab3d-44da-9212-0c3f084c3e69'	System	29 Aug 2020 01:35:08
User entered '28 Aug 2020 20:35'	System	29 Aug 2020 01:35:08

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Aug 2020 20:21'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 2'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53



**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'None (0)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered 'No (N)'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-29T18:09:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f1901a8f-c263-4705-b585-7cab3b4c5ca8' User entered '29 Aug 2020 18:09'	System	29 Aug 2020 23:09:53
	System	29 Aug 2020 23:09:53

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:42:59



**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 3'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520' User entered 'None (0)'	System	31 Aug 2020 01:23:57
	System	31 Aug 2020 01:23:57



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520'	System	31 Aug 2020 01:23:57
User entered 'No (N)'	System	31 Aug 2020 01:23:57

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-30T20:23:47', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '91840225-78fe-4d74-954d-25755b7a8520'	System	31 Aug 2020 01:23:57
User entered '30 Aug 2020 20:23'	System	31 Aug 2020 01:23:57

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 4'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:31', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'None (0)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9' User entered 'No (N)'	System	31 Aug 2020 23:02:52
	System	31 Aug 2020 23:02:52

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-08-31T18:02:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd5ba1ba9-4edf-481c-a257-2f4365250df9'	System	31 Aug 2020 23:02:52
User entered '31 Aug 2020 18:02'	System	31 Aug 2020 23:02:52

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 5'	System	28 Aug 2020 21:42:59



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d'	System	02 Sep 2020 00:48:24
User entered 'No interference with activity (1)'	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'None (0)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:09', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'None (0)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'None (0)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'None (0)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'None (0)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered 'No (N)'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-01T19:48:21', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3123185f-97e1-4609-b19e-fe6c60749b8d' User entered '01 Sep 2020 19:48'	System	02 Sep 2020 00:48:24
	System	02 Sep 2020 00:48:24



**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 6'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:21', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:25', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:26', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2' User entered 'None (0)'	System	03 Sep 2020 01:59:47
	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2'	System	03 Sep 2020 01:59:47
User entered 'No (N)'	System	03 Sep 2020 01:59:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-02T20:59:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0a4bbb1a-6a6e-40f9-bf41-5289a1db8cf2'	System	03 Sep 2020 01:59:47
User entered '02 Sep 2020 20:59'	System	03 Sep 2020 01:59:47

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 7'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:31', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47



US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'None (0)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered 'No (N)'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

**US3312379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-03T20:12:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '08d2c055-09fd-417c-976e-18c6627fed3e' User entered '03 Sep 2020 20:12'	System	04 Sep 2020 01:12:47
	System	04 Sep 2020 01:12:47

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:42:59

US3312379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:42:59



**US3312379**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:59:49

US3312379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '4 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:59:49

US3312379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:59:49

US3312379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4)	09 Sep 2020 14:59:49
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 14:59:55

US3312379

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'I'	System	09 Sep 2020 14:59:55

**US3312379**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 20:34:19

US3312379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 20:34:19



US3312379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 20:34:19

US3312379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4)	11 Sep 2020 20:34:19
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 20:34:22

**US3312379**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:49:47
User entered 'I'	System	11 Sep 2020 20:34:22

**US3312379**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	22 Sep 2020 13:16:02
	(b) (4)	

**US3312379**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '18 Sep 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	22 Sep 2020 13:16:02

**US3312379**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4)	22 Sep 2020 13:16:02
	(b) (4)	

US3312379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	22 Sep 2020 13:16:02
	(b) (4)	



**US3312379**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	22 Sep 2020 13:16:10
	(b) (4)	

**US3312379**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:13
User entered 'I'	System	22 Sep 2020 13:16:10

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:30

US3312379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:11:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'confirmed 23oct2020 is for visit 3 day 57. updated in edc' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:14:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:57:12
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:02:30

US3312379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:30

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'VISIT2'	System	25 Sep 2020 20:02:30

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:35:43



**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:00:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '13:44'	(b) (4)	18 Oct 2020 23:35:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '25 Sep 2020 13:44'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '98.6' F	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '86'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'bpm'	System	18 Oct 2020 23:35:43



US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'breaths/min'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '107'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '63'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43



US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '15:27'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '25 Sep 2020 15:27'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '98.5' F	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '68'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'bpm'	System	18 Oct 2020 23:35:43



US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'breaths/min'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '125'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '79'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'mmHg'	System	18 Oct 2020 23:35:43

US3312379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:35:53

US3312379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4)	18 Oct 2020 23:35:53
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

US3312379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

US3312379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:00:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:03

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	18 Oct 2020 23:36:03



**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:00:15**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:00:15**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:00:15**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14:56'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '25 Sep 2020 14:56'	System	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:51



US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'ONCE'	System	25 Sep 2020 20:02:51

US3312379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:16

US3312379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4)	18 Oct 2020 23:36:16
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14:15'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:16

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '25 Sep 2020 14:15'	System	18 Oct 2020 23:36:16

US3312379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '25 Sep 2020'	(b) (4)	18 Oct 2020 23:36:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25



US3312379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14:12'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '25 Sep 2020 14:12'	System	18 Oct 2020 23:36:25

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25

US3312379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:00:15**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:25

**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	18 Oct 2020 23:36:25

US3312379

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:02:58



**US3312379**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'I'	System	25 Sep 2020 20:02:58

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '831cdf7d-9c6c-4f2c-8014-fbdde1de36fa' User entered 'Yes (Y)'	System	25 Sep 2020 20:27:40
	System	25 Sep 2020 20:27:40

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '831cdf7d-9c6c-4f2c-8014-fbdde1de36fa' User entered '98.5'	System	25 Sep 2020 20:27:40
	System	25 Sep 2020 20:27:40

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '831cdf7d-9c6c-4f2c-8014-fbdde1de36fa'	System	25 Sep 2020 20:27:40
User entered 'No (N)'	System	25 Sep 2020 20:27:40

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '831cdf7d-9c6c-4f2c-8014-fbdde1de36fa' User entered '25 Sep 2020 15:27'	System	25 Sep 2020 20:27:40
	System	25 Sep 2020 20:27:40

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 15:16'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:39:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e7aa48cf-652e-48f5-8875-e495d21ec3eb' User entered 'Yes (Y)'	System	26 Sep 2020 00:41:22
	System	26 Sep 2020 00:41:22

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e7aa48cf-652e-48f5-8875-e495d21ec3eb' User entered '98.6'	System	26 Sep 2020 00:41:22
	System	26 Sep 2020 00:41:22

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:09', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e7aa48cf-652e-48f5-8875-e495d21ec3eb' User entered 'No (N)'	System	26 Sep 2020 00:41:22
	System	26 Sep 2020 00:41:22

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e7aa48cf-652e-48f5-8875-e495d21ec3eb' User entered '25 Sep 2020 19:41'	System	26 Sep 2020 00:41:22
	System	26 Sep 2020 00:41:22

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 18:41'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 2'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered 'Yes (Y)'	System	26 Sep 2020 22:15:16
	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered '99.1'	System	26 Sep 2020 22:15:16
	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:08', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b'	System	26 Sep 2020 22:15:16
User entered 'Yes (Y)'	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 06:11:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered '1'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:36:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Sep 2020 22:15:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered '1'	System	26 Sep 2020 22:15:16
User entered '1'	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered '0'	System	26 Sep 2020 22:15:16
	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a8086af6-1ac4-483c-bf4a-9fb4460ee39b' User entered '26 Sep 2020 17:15'	System	26 Sep 2020 22:15:16
	System	26 Sep 2020 22:15:16

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 3'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:08:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8' User entered 'Yes (Y)'	System	27 Sep 2020 23:09:11
	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:02', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8' User entered '98.2'	System	27 Sep 2020 23:09:11
	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8'	System	27 Sep 2020 23:09:11
User entered 'Yes (Y)'	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 06:11:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8' User entered '1'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Sep 2020 23:09:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8' User entered '1'	System	27 Sep 2020 23:09:11
User entered '1'	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8' User entered '0'	System	27 Sep 2020 23:09:11
	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:08', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'f6d9c8d1-645f-4ee7-be8e-cf63d39091a8'	System	27 Sep 2020 23:09:11
User entered '27 Sep 2020 18:09'	System	27 Sep 2020 23:09:11

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 4'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:28', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '689b1a2d-4f5e-43fa-bb7c-bed03f0ff1c6' User entered 'Yes (Y)'	System	28 Sep 2020 23:19:38
	System	28 Sep 2020 23:19:38

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:31', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '689b1a2d-4f5e-43fa-bb7c-bed03f0ff1c6' User entered '97.8'	System	28 Sep 2020 23:19:38
	System	28 Sep 2020 23:19:38

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '689b1a2d-4f5e-43fa-bb7c-bed03f0ff1c6'	System	28 Sep 2020 23:19:38
User entered 'No (N)'	System	28 Sep 2020 23:19:38

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '689b1a2d-4f5e-43fa-bb7c-bed03f0ff1c6'	System	28 Sep 2020 23:19:38
User entered '28 Sep 2020 18:19'	System	28 Sep 2020 23:19:38

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 5'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b2bb409-ae5c-447e-9c3b-b1edac18a90c' User entered 'Yes (Y)'	System	29 Sep 2020 23:32:33
	System	29 Sep 2020 23:32:33

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b2bb409-ae5c-447e-9c3b-b1edac18a90c' User entered '97.9'	System	29 Sep 2020 23:32:33
	System	29 Sep 2020 23:32:33

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b2bb409-ae5c-447e-9c3b-b1edac18a90c' User entered 'No (N)'	System	29 Sep 2020 23:32:33
	System	29 Sep 2020 23:32:33

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b2bb409-ae5c-447e-9c3b-b1edac18a90c' User entered '29 Sep 2020 18:32'	System	29 Sep 2020 23:32:33
	System	29 Sep 2020 23:32:33

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 6'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3b2a779d-3a1e-4dbe-b829-b6bf3badfadd' User entered 'Yes (Y)'	System	01 Oct 2020 00:44:43
	System	01 Oct 2020 00:44:43

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3b2a779d-3a1e-4dbe-b829-b6bf3badfadd' User entered '97.9'	System	01 Oct 2020 00:44:43
	System	01 Oct 2020 00:44:43

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:39', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3b2a779d-3a1e-4dbe-b829-b6bf3badfadd' User entered 'No (N)'	System	01 Oct 2020 00:44:43
	System	01 Oct 2020 00:44:43

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '3b2a779d-3a1e-4dbe-b829-b6bf3badfadd' User entered '30 Sep 2020 19:44'	System	01 Oct 2020 00:44:43
	System	01 Oct 2020 00:44:43

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 7'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'db90a6dd-a35d-424d-ae37-129119fbad2d' User entered 'Yes (Y)'	System	02 Oct 2020 02:05:49
	System	02 Oct 2020 02:05:49



US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'db90a6dd-a35d-424d-ae37-129119fbad2d' User entered '98.3'	System	02 Oct 2020 02:05:49
	System	02 Oct 2020 02:05:49

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'db90a6dd-a35d-424d-ae37-129119fbad2d' User entered 'No (N)'	System	02 Oct 2020 02:05:49
	System	02 Oct 2020 02:05:49

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'db90a6dd-a35d-424d-ae37-129119fbad2d' User entered '01 Oct 2020 21:05'	System	02 Oct 2020 02:05:49
	System	02 Oct 2020 02:05:49

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:46', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '177aa7aa-78e1-4333-89ff-9d50fa689deb' User entered 'None (1)'	System	25 Sep 2020 20:28:03
	System	25 Sep 2020 20:28:03

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:49', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '177aa7aa-78e1-4333-89ff-9d50fa689deb' User entered 'No (N)'	System	25 Sep 2020 20:28:03
	System	25 Sep 2020 20:28:03



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '177aa7aa-78e1-4333-89ff-9d50fa689deb' User entered 'No (N)'	System	25 Sep 2020 20:28:03
	System	25 Sep 2020 20:28:03

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '177aa7aa-78e1-4333-89ff-9d50fa689deb'	System	25 Sep 2020 20:28:03
User entered 'None (1)'	System	25 Sep 2020 20:28:03

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '177aa7aa-78e1-4333-89ff-9d50fa689deb' User entered '25 Sep 2020 15:27'	System	25 Sep 2020 20:28:03
	System	25 Sep 2020 20:28:03

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 15:16'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0becfb4a-dbf4-47da-ba8a-847891386a99'	System	26 Sep 2020 00:41:38
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 00:41:38

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:22', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0becfb4a-dbf4-47da-ba8a-847891386a99'	System	26 Sep 2020 00:41:38
User entered 'No (N)'	System	26 Sep 2020 00:41:38



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0becfb4a-dbf4-47da-ba8a-847891386a99'	System	26 Sep 2020 00:41:38
User entered 'No (N)'	System	26 Sep 2020 00:41:38

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0becfb4a-dbfc-47da-ba8a-847891386a99'	System	26 Sep 2020 00:41:38
User entered 'None (1)'	System	26 Sep 2020 00:41:38

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '0becfb4a-dbf4-47da-ba8a-847891386a99'	System	26 Sep 2020 00:41:38
User entered '25 Sep 2020 19:41'	System	26 Sep 2020 00:41:38

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 18:41'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 2'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:17', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e'	System	26 Sep 2020 22:17:37
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:15:19', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered 'Yes (Y)'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered '50'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered 'Yes (Y)'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered '50'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered 'None (1)'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'b4dbbd18-8580-45eb-8827-ba37d955b65e' User entered '26 Sep 2020 17:17'	System	26 Sep 2020 22:17:37
	System	26 Sep 2020 22:17:37

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 3'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:25', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered 'Yes (Y)'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:10:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered '58'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:10:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered 'Yes (Y)'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:11:11', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered '60'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:11:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:11:18

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:11:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7a0e553e-d2f3-4d60-a09e-ed4284fc2882'	System	27 Sep 2020 23:11:18
User entered '27 Sep 2020 18:11'	System	27 Sep 2020 23:11:18

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 4'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00'	System	28 Sep 2020 23:19:54
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 23:19:54

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00' User entered 'No (N)'	System	28 Sep 2020 23:19:54
	System	28 Sep 2020 23:19:54

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:47', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00'	System	28 Sep 2020 23:19:54
User entered 'Yes (Y)'	System	28 Sep 2020 23:19:54

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:49', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00' User entered '25'	System	28 Sep 2020 23:19:54
	System	28 Sep 2020 23:19:54

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00'	System	28 Sep 2020 23:19:54
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 23:19:54

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '40ac3440-7250-48b4-bfc0-be67cf643f00' User entered '28 Sep 2020 18:19'	System	28 Sep 2020 23:19:54
	System	28 Sep 2020 23:19:54



**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 5'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6'	System	29 Sep 2020 23:33:26
User entered 'None (1)'	System	29 Sep 2020 23:33:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6' User entered 'No (N)'	System	29 Sep 2020 23:33:26
	System	29 Sep 2020 23:33:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6' User entered 'Yes (Y)'	System	29 Sep 2020 23:33:26
	System	29 Sep 2020 23:33:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:19', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6' User entered '35'	System	29 Sep 2020 23:33:26
	System	29 Sep 2020 23:33:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:21', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6'	System	29 Sep 2020 23:33:26
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 23:33:26



**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:33:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'fff8b66b-cad0-460c-97cb-8357c1c35ea6' User entered '29 Sep 2020 18:33'	System	29 Sep 2020 23:33:26
	System	29 Sep 2020 23:33:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 6'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:43:32', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered 'None (1)'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:43:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered 'No (N)'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:43:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered 'Yes (Y)'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered '20'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered 'None (1)'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a55b3686-9246-438a-a895-23c3bb7982bf' User entered '30 Sep 2020 19:44'	System	01 Oct 2020 00:44:26
	System	01 Oct 2020 00:44:26

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 7'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042'	System	02 Oct 2020 02:06:36
User entered 'None (1)'	System	02 Oct 2020 02:06:36

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042'	System	02 Oct 2020 02:06:36
User entered 'No (N)'	System	02 Oct 2020 02:06:36

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042' User entered 'Yes (Y)'	System	02 Oct 2020 02:06:36
	System	02 Oct 2020 02:06:36



US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042' User entered '15'	System	02 Oct 2020 02:06:36
	System	02 Oct 2020 02:06:36

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042'	System	02 Oct 2020 02:06:36
User entered 'None (1)'	System	02 Oct 2020 02:06:36

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2068571a-2c6f-4995-a392-1d9f39a28042'	System	02 Oct 2020 02:06:36
User entered '01 Oct 2020 21:06'	System	02 Oct 2020 02:06:36

US3312379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:27:59', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:03', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:05', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered 'None (0)'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:09', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892'	System	25 Sep 2020 20:28:15
User entered 'No (N)'	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T15:28:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2de77f2c-dc6c-493e-9068-dfa1d5158892' User entered '25 Sep 2020 15:28'	System	25 Sep 2020 20:28:15
	System	25 Sep 2020 20:28:15

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 15:16'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:39', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'None (0)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered 'No (N)'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-25T19:41:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '68150f54-660c-40c2-ba06-4707c53d5ba7' User entered '25 Sep 2020 19:41'	System	26 Sep 2020 00:41:50
	System	26 Sep 2020 00:41:50

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '25 Sep 2020 18:41'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 2'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435'	System	26 Sep 2020 22:17:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 22:17:55

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:42', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'None (0)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'None (0)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:44', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'None (0)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'None (0)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:47', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'None (0)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:49', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered 'No (N)'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-26T17:17:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9d1314fe-eb79-4260-8d18-7900d382f435' User entered '26 Sep 2020 17:17'	System	26 Sep 2020 22:17:55
	System	26 Sep 2020 22:17:55

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 3'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Sep 2020 23:09:23



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered 'None (0)'	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492' User entered 'None (0)'	System	27 Sep 2020 23:09:23
	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered 'None (0)'	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492' User entered 'None (0)'	System	27 Sep 2020 23:09:23
	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered 'None (0)'	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered 'No (N)'	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-27T18:09:19', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'a5a27871-8cb7-4e1f-9593-ed640c07b492'	System	27 Sep 2020 23:09:23
User entered '27 Sep 2020 18:09'	System	27 Sep 2020 23:09:23

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 4'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c'	System	28 Sep 2020 23:20:08
User entered 'No interference with activity (1)'	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'None (0)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:19:58', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'None (0)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:20:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'None (0)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:20:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'None (0)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:20:02', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'None (0)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:20:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered 'No (N)'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-28T18:20:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cee893b0-b5b6-437b-8114-2241f6c1399c' User entered '28 Sep 2020 18:20'	System	28 Sep 2020 23:20:08
	System	28 Sep 2020 23:20:08

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 5'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:35', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:36', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:38', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'None (0)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:39', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered 'No (N)'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-29T18:32:41', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7147ff04-d3d4-4590-b9b4-b1ea8666624c' User entered '29 Sep 2020 18:32'	System	29 Sep 2020 23:32:44
	System	29 Sep 2020 23:32:44

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 6'	System	25 Sep 2020 20:02:51



US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:25', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:26', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:28', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'None (0)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered 'No (N)'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-09-30T19:44:32', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7330cb18-66d4-4156-a996-22c6f30e0e90' User entered '30 Sep 2020 19:44'	System	01 Oct 2020 00:44:35
	System	01 Oct 2020 00:44:35



**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:02:51

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	25 Sep 2020 20:02:51
User entered 'Day 7'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:49', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:50', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04



**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:00:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:53', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'None (0)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:05:59', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered 'No (N)'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-01T21:06:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'cdc98d8d-44e1-4f3b-8973-c7611ce52698' User entered '01 Oct 2020 21:06'	System	02 Oct 2020 02:06:04
	System	02 Oct 2020 02:06:04

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:02:51

US3312379

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:00:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	01 Oct 2020 00:44:26
User entered 'Day 8'	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-02T23:34:20', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e16d30a6-33c0-4252-b545-2f517c06bba5' User entered 'No (N)'	System	03 Oct 2020 04:34:27
	System	03 Oct 2020 04:34:27

US3312379

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-02T23:34:23', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e16d30a6-33c0-4252-b545-2f517c06bba5' User entered '02 Oct 2020 23:34'	System	03 Oct 2020 04:34:27
	System	03 Oct 2020 04:34:27



**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:00:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 00:44:26

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	01 Oct 2020 00:44:26
User entered 'Day 8'	System	01 Oct 2020 00:44:26

US3312379

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:00:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-02T23:34:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8371d288-3507-4f83-b56c-015433d8144c' User entered 'No (N)'	System	03 Oct 2020 04:34:35
	System	03 Oct 2020 04:34:35

US3312379

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:00:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45920B03-326B-4876-9C97-B3D5AE84EA5E)', Time: '2020-10-02T23:34:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8371d288-3507-4f83-b56c-015433d8144c' User entered '02 Oct 2020 23:34'	System	03 Oct 2020 04:34:35
	System	03 Oct 2020 04:34:35

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 00:44:26

**US3312379**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:00:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 00:44:26

**US3312379**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:25



US3312379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:25

**US3312379**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:25

US3312379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:25

US3312379

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:37:30

**US3312379**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'I'	System	18 Oct 2020 23:37:30

US3312379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:50

US3312379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '09 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:50

US3312379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:37:50



US3312379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:37:50
	(b) (4)	

US3312379

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:37:54

**US3312379**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'I'	System	18 Oct 2020 23:37:54

**US3312379**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:38:20

US3312379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '16 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:38:20

**US3312379**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:38:20

US3312379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:38:20

US3312379

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:38:25



**US3312379**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'I'	System	18 Oct 2020 23:38:25

US3312379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:16

US3312379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '23 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:16

US3312379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:16

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'VISIT3'	System	06 Nov 2020 00:13:16

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '23 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '13:16'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40



**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered '23 Oct 2020 13:16'	System	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '98.5' F	(b) (4)	06 Nov 2020 00:13:40
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'bpm'	System	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'breaths/min'	System	06 Nov 2020 00:13:40



US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '101'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'mmHg'	System	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '62'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'mmHg'	System	06 Nov 2020 00:13:40

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42

US3312379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42

US3312379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'No (N)'	(b) (4)	06 Nov 2020 00:13:47
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:47



**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:57

US3312379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '23 Oct 2020'	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:13:57
	(b) (4)	

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered '13:24'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:13:57

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered '23 Oct 2020 13:24'	System	06 Nov 2020 00:13:57

US3312379

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:43:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:14:01

**US3312379**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'I'	System	06 Nov 2020 00:14:01

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 64'	System	28 Aug 2020 21:42:59

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-10-30T12:31:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'febb0529-d123-4086-ab43-2d92e332d844'	System	30 Oct 2020 17:32:12
User entered 'Yes (Y)'	System	30 Oct 2020 17:32:12



US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-10-30T12:31:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'febb0529-d123-4086-ab43-2d92e332d844'	System	30 Oct 2020 17:32:12
User entered 'No (N)'	System	30 Oct 2020 17:32:12

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-10-30T12:31:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'febb0529-d123-4086-ab43-2d92e332d844'	System	30 Oct 2020 17:32:12
User entered 'No (N)'	System	30 Oct 2020 17:32:12

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-10-30T12:32:03', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'febb0529-d123-4086-ab43-2d92e332d844'	System	30 Oct 2020 17:32:12
User entered 'No (N)'	System	30 Oct 2020 17:32:12

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-10-30T12:32:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'febb0529-d123-4086-ab43-2d92e332d844' User entered '30 Oct 2020 12:32:07'	System	30 Oct 2020 17:32:12
	System	30 Oct 2020 17:32:12

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 71'	System	28 Aug 2020 21:42:59

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-06T12:00:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ead1b5e-2f57-4a9f-a358-279246baf4b4'	System	06 Nov 2020 18:01:13
User entered 'Yes (Y)'	System	06 Nov 2020 18:01:13



US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-06T12:00:30', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ead1b5e-2f57-4a9f-a358-279246baf4b4'	System	06 Nov 2020 18:01:13
User entered 'No (N)'	System	06 Nov 2020 18:01:13

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-06T12:00:33', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ead1b5e-2f57-4a9f-a358-279246baf4b4'	System	06 Nov 2020 18:01:13
User entered 'No (N)'	System	06 Nov 2020 18:01:13

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-06T12:00:39', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ead1b5e-2f57-4a9f-a358-279246baf4b4'	System	06 Nov 2020 18:01:13
User entered 'No (N)'	System	06 Nov 2020 18:01:13

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-06T12:00:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ead1b5e-2f57-4a9f-a358-279246baf4b4' User entered '06 Nov 2020 12:00:43'	System	06 Nov 2020 18:01:13
	System	06 Nov 2020 18:01:13

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered 'Day 78'	System	28 Aug 2020 21:42:59

US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-11T22:34:02', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2d25c45d-77f0-4e83-8eb2-8ac3299d9b67'	System	12 Nov 2020 04:34:22
User entered 'No (N)'	System	12 Nov 2020 04:34:22



US3312379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-11T22:34:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2d25c45d-77f0-4e83-8eb2-8ac3299d9b67'	System	12 Nov 2020 04:34:22
User entered 'No (N)'	System	12 Nov 2020 04:34:22

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-11T22:34:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '2d25c45d-77f0-4e83-8eb2-8ac3299d9b67' User entered '11 Nov 2020 22:34:18'	System	12 Nov 2020 04:34:22
	System	12 Nov 2020 04:34:22

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:33
Data entry locked.	System	28 Aug 2020 21:42:59
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 21:42:59

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:14:05

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:11:25
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SUBJECT CONTACTED AND CONFIRMED NEW MED HISTORY , CON MED AND PROCEDURE UPDATED FOR RIGHT MENISCUS TEAR AND REPAIR. NO WORSENING, NOT AN AE.' (Site from DM).	Monica Atwood (b) (4)	21 Dec 2020 20:03:42
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:00:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:26:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df'	System	25 Nov 2020 00:27:17
User entered 'Yes (Y)'	System	25 Nov 2020 00:27:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:26:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df' User entered 'No (N)'	System	25 Nov 2020 00:27:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:26:59', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df' User entered 'No (N)'	System	25 Nov 2020 00:27:17



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:27:01', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df' User entered 'Yes (Y)'	System	25 Nov 2020 00:27:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:27:04', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df'	System	25 Nov 2020 00:27:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 00:27:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-24T18:27:06', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '28f44d5e-d331-4866-9cfd-06a0987424df' User entered '24 Nov 2020 18:27:06'	System	25 Nov 2020 00:27:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-29T09:44:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '158815eb-0dee-4380-a895-11ac92698510' User entered 'No (N)'	System	29 Nov 2020 15:44:21
	System	29 Nov 2020 15:44:21

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-29T09:44:14', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '158815eb-0dee-4380-a895-11ac92698510'	System	29 Nov 2020 15:44:21
User entered 'No (N)'	System	29 Nov 2020 15:44:21



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-11-29T09:44:17', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '158815eb-0dee-4380-a895-11ac92698510' User entered '29 Nov 2020 09:44:17'	System	29 Nov 2020 15:44:21
	System	29 Nov 2020 15:44:21

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-08T12:04:10', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '44654b12-e2b6-419d-9c46-3596d16af0a7'	System	08 Dec 2020 18:04:18
User entered 'No (N)'	System	08 Dec 2020 18:04:18

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-08T12:04:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '44654b12-e2b6-419d-9c46-3596d16af0a7'	System	08 Dec 2020 18:04:18
User entered 'No (N)'	System	08 Dec 2020 18:04:18

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-08T12:04:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '44654b12-e2b6-419d-9c46-3596d16af0a7' User entered '08 Dec 2020 12:04:15'	System	08 Dec 2020 18:04:18
	System	08 Dec 2020 18:04:18

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-14T16:43:27', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ae919241-7595-4b15-ac59-7d7c942e7102'	System	14 Dec 2020 22:43:33
User entered 'No (N)'	System	14 Dec 2020 22:43:33

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-14T16:43:24', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ae919241-7595-4b15-ac59-7d7c942e7102'	System	14 Dec 2020 22:43:33
User entered 'No (N)'	System	14 Dec 2020 22:43:33

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-14T16:43:29', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ae919241-7595-4b15-ac59-7d7c942e7102'	System	14 Dec 2020 22:43:33
User entered '14 Dec 2020 16:43:29'	System	14 Dec 2020 22:43:33

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-20T09:37:34', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '60f43047-8675-4a45-9322-2571a49038f4' User entered 'No (N)'	System	20 Dec 2020 15:37:43

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-20T09:37:37', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '60f43047-8675-4a45-9322-2571a49038f4' User entered 'No (N)'	System	20 Dec 2020 15:37:43
	System	20 Dec 2020 15:37:43

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-20T09:37:39', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '60f43047-8675-4a45-9322-2571a49038f4' User entered '20 Dec 2020 09:37:39'	System	20 Dec 2020 15:37:43
	System	20 Dec 2020 15:37:43

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-27T08:12:51', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '57f5f42f-cde5-453d-b3cb-e355d61cf8a3'	System	27 Dec 2020 14:12:59
User entered 'No (N)'	System	27 Dec 2020 14:12:59

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-27T08:12:54', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '57f5f42f-cde5-453d-b3cb-e355d61cf8a3'	System	27 Dec 2020 14:12:59
User entered 'No (N)'	System	27 Dec 2020 14:12:59



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2020-12-27T08:12:57', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '57f5f42f-cde5-453d-b3cb-e355d61cf8a3' User entered '27 Dec 2020 08:12:57'	System	27 Dec 2020 14:12:59
	System	27 Dec 2020 14:12:59

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-03T07:44:48', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '5982a465-7b8f-4356-9d04-3f575852600c' User entered 'No (N)'	System	03 Jan 2021 13:45:01
	System	03 Jan 2021 13:45:01

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-03T07:44:52', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '5982a465-7b8f-4356-9d04-3f575852600c' User entered 'No (N)'	System	03 Jan 2021 13:45:01
	System	03 Jan 2021 13:45:01

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-03T07:44:56', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '5982a465-7b8f-4356-9d04-3f575852600c' User entered '03 Jan 2021 07:44:56'	System	03 Jan 2021 13:45:01
	System	03 Jan 2021 13:45:01

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-13T17:18:05', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ff1e79d2-6ff6-4cc0-8c58-5241b30a36b6'	System	13 Jan 2021 23:18:15
User entered 'No (N)'	System	13 Jan 2021 23:18:15

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-13T17:18:03', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ff1e79d2-6ff6-4cc0-8c58-5241b30a36b6'	System	13 Jan 2021 23:18:15
User entered 'No (N)'	System	13 Jan 2021 23:18:15

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-13T17:18:12', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ff1e79d2-6ff6-4cc0-8c58-5241b30a36b6' User entered '13 Jan 2021 17:18:12'	System	13 Jan 2021 23:18:15
	System	13 Jan 2021 23:18:15

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:03', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b' User entered 'Yes (Y)'	System	19 Jan 2021 18:53:27
	System	19 Jan 2021 18:53:27

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:05', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b' User entered 'No (N)'	System	19 Jan 2021 18:53:27
	System	19 Jan 2021 18:53:27

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:07', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b' User entered 'No (N)'	System	19 Jan 2021 18:53:27

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:09', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b' User entered 'Yes (Y)'	System	19 Jan 2021 18:53:27
	System	19 Jan 2021 18:53:27

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:11', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b'	System	19 Jan 2021 18:53:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 18:53:27

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-19T12:53:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ed2d5752-3ec5-4f09-92f7-ad9cc65f7a5b' User entered '19 Jan 2021 12:53:18'	System	19 Jan 2021 18:53:27
	System	19 Jan 2021 18:53:27

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-24T06:56:13', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '65b523c3-551e-4db5-ab5b-0a88698c31e1' User entered 'No (N)'	System	24 Jan 2021 12:56:20
	System	24 Jan 2021 12:56:20

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-24T06:56:16', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '65b523c3-551e-4db5-ab5b-0a88698c31e1' User entered 'No (N)'	System	24 Jan 2021 12:56:20
	System	24 Jan 2021 12:56:20

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-01-24T06:56:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '65b523c3-551e-4db5-ab5b-0a88698c31e1' User entered '24 Jan 2021 06:56:18'	System	24 Jan 2021 12:56:20
	System	24 Jan 2021 12:56:20

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-02T12:00:15', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b5fc54f-70a2-4a8e-a46d-32dd9b4a6009' User entered 'No (N)'	System	02 Feb 2021 18:00:32



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-02T12:00:18', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b5fc54f-70a2-4a8e-a46d-32dd9b4a6009'	System	02 Feb 2021 18:00:32
User entered 'No (N)'	System	02 Feb 2021 18:00:32

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-02T12:00:20', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7b5fc54f-70a2-4a8e-a46d-32dd9b4a6009' User entered '02 Feb 2021 12:00:20'	System	02 Feb 2021 18:00:32
	System	02 Feb 2021 18:00:32

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-09T12:00:19', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9b69f767-79bf-41a2-bcb9-4284ce2f5a7f' User entered 'No (N)'	System	09 Feb 2021 18:00:38
	System	09 Feb 2021 18:00:38

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-09T12:00:20', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9b69f767-79bf-41a2-bcb9-4284ce2f5a7f' User entered 'No (N)'	System	09 Feb 2021 18:00:38
	System	09 Feb 2021 18:00:38

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-09T12:00:22', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9b69f767-79bf-41a2-bcb9-4284ce2f5a7f' User entered '09 Feb 2021 12:00:22'	System	09 Feb 2021 18:00:38
	System	09 Feb 2021 18:00:38



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-14T07:50:40', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '43858a7a-6af9-4752-91dc-49690e03c309' User entered 'No (N)'	System	14 Feb 2021 13:50:47
	System	14 Feb 2021 13:50:47

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-14T07:50:43', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '43858a7a-6af9-4752-91dc-49690e03c309' User entered 'No (N)'	System	14 Feb 2021 13:50:47
	System	14 Feb 2021 13:50:47

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-14T07:50:45', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '43858a7a-6af9-4752-91dc-49690e03c309' User entered '14 Feb 2021 07:50:45'	System	14 Feb 2021 13:50:47
	System	14 Feb 2021 13:50:47

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-21T09:08:58', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd6aae4af-4808-433e-a6ed-de3565fe93f3'	System	21 Feb 2021 15:09:07
User entered 'No (N)'	System	21 Feb 2021 15:09:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-21T09:09:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd6aae4af-4808-433e-a6ed-de3565fe93f3'	System	21 Feb 2021 15:09:07
User entered 'No (N)'	System	21 Feb 2021 15:09:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-02-21T09:09:03', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd6aae4af-4808-433e-a6ed-de3565fe93f3' User entered '21 Feb 2021 09:09:03'	System	21 Feb 2021 15:09:07
	System	21 Feb 2021 15:09:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:41-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered 'Yes (Y)'	System	02 Mar 2021 18:02:17



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:44-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered 'No (N)'	System	02 Mar 2021 18:02:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:50-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered 'No (N)'	System	02 Mar 2021 18:02:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:54-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered 'Yes (Y)'	System	02 Mar 2021 18:02:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:58-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Mar 2021 18:02:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:01:00-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '1fe7a85e-4747-4c08-b572-90b97711dffc'	System	02 Mar 2021 18:02:17
User entered '02 Mar 2021 12:01:00'	System	02 Mar 2021 18:02:17

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-09T16:57:57-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8879376d-7c5e-4447-b9b6-af5811a0bf69'	System	09 Mar 2021 22:58:07
User entered 'No (N)'	System	09 Mar 2021 22:58:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-09T16:57:58-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8879376d-7c5e-4447-b9b6-af5811a0bf69'	System	09 Mar 2021 22:58:07
User entered 'No (N)'	System	09 Mar 2021 22:58:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-09T16:58:00-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '8879376d-7c5e-4447-b9b6-af5811a0bf69'	System	09 Mar 2021 22:58:07
User entered '09 Mar 2021 16:58:00'	System	09 Mar 2021 22:58:07

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:11-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c' User entered 'Yes (Y)'	System	16 Mar 2021 12:44:39
	System	16 Mar 2021 12:44:39

US3312379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:15

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:15-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c' User entered 'No (N)'	System	16 Mar 2021 12:44:39
	System	16 Mar 2021 12:44:39



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:19-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c' User entered 'No (N)'	System	16 Mar 2021 12:44:39
	System	16 Mar 2021 12:44:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:22-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c'	System	16 Mar 2021 12:44:39
User entered 'Yes (Y)'	System	16 Mar 2021 12:44:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:24-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c'	System	16 Mar 2021 12:44:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Mar 2021 12:44:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-16T07:44:30-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '06ab103a-3b95-4ba9-8e30-f3a75ce2010c' User entered '16 Mar 2021 07:44:30'	System	16 Mar 2021 12:44:39
	System	16 Mar 2021 12:44:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-23T15:59:58-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e68afe77-c0d9-4f16-8d8a-2570d29068b7'	System	23 Mar 2021 21:00:08
User entered 'No (N)'	System	23 Mar 2021 21:00:08



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-23T15:59:59-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e68afe77-c0d9-4f16-8d8a-2570d29068b7'	System	23 Mar 2021 21:00:08
User entered 'No (N)'	System	23 Mar 2021 21:00:08

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-23T16:00:02-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'e68afe77-c0d9-4f16-8d8a-2570d29068b7' User entered '23 Mar 2021 16:00:02'	System	23 Mar 2021 21:00:08
	System	23 Mar 2021 21:00:08

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-30T13:30:29-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '26c89bd0-c5d3-457a-b504-6631b3609d87'	System	30 Mar 2021 18:30:39
User entered 'No (N)'	System	30 Mar 2021 18:30:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-30T13:30:31-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '26c89bd0-c5d3-457a-b504-6631b3609d87'	System	30 Mar 2021 18:30:39
User entered 'No (N)'	System	30 Mar 2021 18:30:39

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-30T13:30:33-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '26c89bd0-c5d3-457a-b504-6631b3609d87'	System	30 Mar 2021 18:30:39
User entered '30 Mar 2021 13:30:33'	System	30 Mar 2021 18:30:39



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-04T05:16:32-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7bae083a-5c7c-45bd-91ed-ed385718f1ac'	System	04 Apr 2021 10:16:38
User entered 'No (N)'	System	04 Apr 2021 10:16:38

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-04T05:16:34-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7bae083a-5c7c-45bd-91ed-ed385718f1ac'	System	04 Apr 2021 10:16:38
User entered 'No (N)'	System	04 Apr 2021 10:16:38

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-04T05:16:36-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '7bae083a-5c7c-45bd-91ed-ed385718f1ac'	System	04 Apr 2021 10:16:38
User entered '04 Apr 2021 05:16:36'	System	04 Apr 2021 10:16:38

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-11T08:16:59-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd84835cc-89fc-495d-84ba-baa35c9b434d' User entered 'No (N)'	System	11 Apr 2021 13:17:06
	System	11 Apr 2021 13:17:06

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-11T08:17:01-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd84835cc-89fc-495d-84ba-baa35c9b434d' User entered 'No (N)'	System	11 Apr 2021 13:17:06
	System	11 Apr 2021 13:17:06

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-11T08:17:03-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'd84835cc-89fc-495d-84ba-baa35c9b434d'	System	11 Apr 2021 13:17:06
User entered '11 Apr 2021 08:17:03'	System	11 Apr 2021 13:17:06

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-18T07:20:05-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '71b7c836-a061-45a7-9bd1-503e300db873'	System	18 Apr 2021 12:20:18
User entered 'No (N)'	System	18 Apr 2021 12:20:18



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-18T07:20:12-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '71b7c836-a061-45a7-9bd1-503e300db873'	System	18 Apr 2021 12:20:18
User entered 'No (N)'	System	18 Apr 2021 12:20:18

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-18T07:20:15-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '71b7c836-a061-45a7-9bd1-503e300db873'	System	18 Apr 2021 12:20:18
User entered '18 Apr 2021 07:20:15'	System	18 Apr 2021 12:20:18

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-25T09:50:58-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ed37ecd-8bb7-41c6-b878-8b07e5d2c9b4'	System	25 Apr 2021 14:51:08
User entered 'No (N)'	System	25 Apr 2021 14:51:08

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

Have you been exposed to someone with 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 (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-25T09:51:00-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ed37ecd-8bb7-41c6-b878-8b07e5d2c9b4'	System	25 Apr 2021 14:51:08
User entered 'No (N)'	System	25 Apr 2021 14:51:08

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-04-25T09:51:04-05:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: '9ed37ecd-8bb7-41c6-b878-8b07e5d2c9b4'	System	25 Apr 2021 14:51:08
User entered '25 Apr 2021 09:51:04'	System	25 Apr 2021 14:51:08



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:14:05



**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:14:05

**US3312379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:14:05
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:14:05

US3312379

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:15

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 16:35:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:33-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ad367f3c-99b3-48a1-97a0-c9b65fb90e91'	System	02 Mar 2021 18:00:50
User entered 'No (N)'	System	02 Mar 2021 18:00:50



**US3312379**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:35:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6885AE0-6867-41E2-ACE8-7F375049E19D)', Time: '2021-03-02T12:00:35-06:00', User OID: 'PatientReportedOutcome (US3312379)', ODM File OID: 'ad367f3c-99b3-48a1-97a0-c9b65fb90e91'	System	02 Mar 2021 18:00:50
User entered '02 Mar 2021 12:00:35'	System	02 Mar 2021 18:00:50

US3312379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User closed query 'Please complete Continuing page for Safety Call Day 85.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:01:59
Query 'Please complete Continuing page for Safety Call Day 85.' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 17:07:49
User opened query 'Please complete Continuing page for Safety Call Day 85.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:43:38
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 21:30:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 21:30:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 21:30:21
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 16:05:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 16:05:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:03:34

US3312379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 13:15:13
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'phone call OOW, deviation noted' (Site from System).	Kelly Moen (b) (4) (b) (4)	17 Dec 2020 20:47:55
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Nov 2020 21:30:21
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 21:30:21
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Nov 2020 16:05:05
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	30 Nov 2020 16:05:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 16:05:05
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 16:03:53
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Nov 2020 16:03:34

US3312379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:03:34

US3312379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:03:34

**US3312379**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:03:34

**US3312379**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Dec 2020 17:07:39

US3312379

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:42
User entered 'I'	System	17 Dec 2020 17:07:39



**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:55

**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:55

**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:55

**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:55

**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:29

**US3312379**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered 'I'	System	22 Dec 2020 20:20:29

**US3312379**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:22:28

**US3312379**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:22:28



**US3312379**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:22:28

**US3312379**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:22:28

US3312379

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:22:16

**US3312379**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered 'I'	System	25 Jan 2021 17:22:16

**US3312379**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:50

**US3312379**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:50

**US3312379**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:50

US3312379

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:50



**US3312379**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:40

**US3312379**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered 'I'	System	22 Feb 2021 15:57:40

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:03

US3312379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:03

US3312379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:03

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered 'VISIT4'	System	02 Apr 2021 16:52:03

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07



**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered empty.	System	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered empty.	System	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07



US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered empty.	System	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered empty.	System	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered empty.	System	02 Apr 2021 16:52:07

US3312379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39

US3312379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:09



US3312379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:09

US3312379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:16

US3312379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:16

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '10:26'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:16

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered '02 Apr 2021 10:26'	System	02 Apr 2021 16:52:16

US3312379

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:52:18

**US3312379**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:18:39
User entered 'I'	System	02 Apr 2021 16:52:18

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:57:08



**US3312379**

**Folder: Covid-19 Assessment 14 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:00:15**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '09:00'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:57:08

**US3312379**

**Folder: Covid-19 Assessment 14 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:00:15**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:54
User entered '14 Sep 2020 09:00'	System	15 Sep 2020 00:57:08

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:57:08

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:57:08

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 00:18:50
User entered 'Day 1 (Day 1)'	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User closed query 'Per CDM: it seems start date on Symptom Log and contact date are the same (14SEP020). Please confirm if this date is the actual start date of symptoms.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:12:16
Query 'Per CDM: it seems start date on Symptom Log and contact date are the same (14SEP020). Please confirm if this date is the actual start date of symptoms.' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:44
User opened query 'Per CDM: it seems start date on Symptom Log and contact date are the same (14SEP020). Please confirm if this date is the actual start date of symptoms.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:51:39
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '100'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User entered '%'	System	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 00:21:08
User entered 'Mild (Mild)'	Karol Moore (b) (4)	15 Sep 2020 00:58:38
	(b) (4)	
	(b) (4), (b) (6)	

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:58:38

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 00:18:50
User entered 'Day 2 (Day 2)'	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '96'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User entered '%'	System	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:28:59



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User entered '%'	System	18 Dec 2020 16:39:18
User entered empty.	System	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22



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Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:22

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '12 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 00:20:30
User entered '12 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 00:19:46
	(b) (4)	



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Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User entered '%'	System	18 Dec 2020 16:39:18
User entered empty.	System	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4)	06 Nov 2020 00:19:46
	Karol Moore (b) (4)	
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:19:46

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 00:22:39
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 00:22:00
	(b) (4)	
User entered 'Mild (Mild)'	Karol Moore (b) (4)	06 Nov 2020 00:19:46
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 00:22:39
User entered 'Mild (Mild)'	Karol Moore (b) (4)	06 Nov 2020 00:19:46
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '13 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User entered '%'	System	18 Dec 2020 16:39:18
User entered empty.	System	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:39:18
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21



US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:20:21

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 00:22:27
User entered 'Mild (Mild)'	Karol Moore (b) (4)	06 Nov 2020 00:20:21
	(b) (4)	

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
Query 'Per CDM: it appears that Illness Visit and Diagnostic Test date are the same (14SEP2020) yet no test result is reported. Please reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Oct 2020 10:48:28
User opened query 'Per CDM: it appears that Illness Visit and Diagnostic Test date are the same (14SEP2020) yet no test result is reported. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:44:39
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 16:45:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 16:45:49
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Nov 2020 16:45:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 00:59:02
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02



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Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[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)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:02

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
User entered '0'	System	18 Nov 2020 16:45:49

US3312379

Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:00:15

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:33:31

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:35:05

**US3312379**

**Folder: Covid-19 Assessment 27 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:00:15**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '12:39'	(b) (4)	06 Nov 2020 00:35:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:29
User entered '27 Oct 2020 12:39'	System	06 Nov 2020 00:35:05



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Safety Call (Safety Call)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:35:05

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Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:15

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 00:35:05
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '21 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:25



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '22 Oct 2020'	(b) (4)	06 Nov 2020 00:38:44
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44



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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:38:44

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '23 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03



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Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

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Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:03

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '24 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:39:23
	(b) (4)	



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '25 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:39:42

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:39:42



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '26 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	18 Dec 2020 17:25:36
User entered empty.	System	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:25:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4)	06 Nov 2020 00:40:02
	Karol Moore (b) (4)	
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98.7' F	(b) (4)	06 Nov 2020 00:40:23
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23



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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:40:23

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 8 (Day 8)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '28 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Folder: Covid-19 Assessment 27 Oct 2020

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Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58



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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	06 Nov 2020 00:42:58

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '99.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58



US3312379

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Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

US3312379

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Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:42:58

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58



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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:42:58

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Generated On: 09 Jun 2021 17:00:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 9 (Day 9)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '29 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '92'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '100.5' F	(b) (4)	06 Nov 2020 00:44:20
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:44:20

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20



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Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

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Form: Symptom Log (9)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:44:20



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '30 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Form: Symptom Log (10)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User entered '%'	System	06 Nov 2020 00:45:00

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98.2' F	(b) (4)	06 Nov 2020 00:45:00
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00



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Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:00

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18



US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[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)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:45:18

US3312379

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:15

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:13:40
User entered '0'	System	06 Nov 2020 00:45:18



US3312379

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:00:15

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:48:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'ACCESSION NUMBER 1F60DCY' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 16:58:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:31:14
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

US3312379

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:00:15

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 17SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 05:27:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 17SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'CORRECT AS ENTERED. SALIVA SAMPLE ILLNESS VISIT DAY 3 IS RECORDED AS 16SEP2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Nov 2020 16:49:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 17SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:14:30
User entered '16 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

US3312379

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:00:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	



**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21



**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:25:21

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

**US3312379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:25:21
	(b) (4)	

US3312379

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:00:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered '29 Oct 2020'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	



**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

US3312379

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:00:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	



**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:56:44



**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

**US3312379**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:56:44
	(b) (4)	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:31

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 00:59:31

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'SICKD1'	System	15 Sep 2020 00:59:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31



**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '11:28'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered '14 Sep 2020 11:28'	System	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '70' in	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31
DataPoint set to visible.	System	15 Sep 2020 00:59:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '246' lb	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31
DataPoint set to visible.	System	15 Sep 2020 00:59:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '80'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31



**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'bpm'	System	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '12'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'breaths/min'	System	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '125'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'mmHg'	System	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'mmHg'	System	15 Sep 2020 01:00:31

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26



**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:00:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:44

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:00:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:44

US3312379

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:15

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 as 17SEP2020. However Saliva Log is not completed. Please reconcile or clarify ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:13:24
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 as 17SEP2020. However Saliva Log is not completed. Please reconcile or clarify ' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:49:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 01:00:53

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:00:53

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 00:54:35
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4)	06 Nov 2020 00:54:35
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:54:35



**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'SICKD1'	System	06 Nov 2020 00:54:35

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 00:55:14
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '13:15'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered '27 Oct 2020 13:15'	System	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '70' in	(b) (4)	06 Nov 2020 00:55:14
DataPoint set to visible.	Karol Moore (b) (4)	06 Nov 2020 00:54:35
	(b) (4)	
	System	

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '246' lb	(b) (4) Karol Moore (b) (4)	06 Nov 2020 00:55:14
DataPoint set to visible.	(b) (4) System	06 Nov 2020 00:54:35

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '98.7' F	(b) (4)	06 Nov 2020 00:55:14
	Karol Moore (b) (4)	
	(b) (4)	



US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '77'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'bpm'	System	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '15'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'breaths/min'	System	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '116'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'mmHg'	System	06 Nov 2020 00:55:14



US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '78'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User entered 'mmHg'	System	06 Nov 2020 00:55:14

**US3312379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26

US3312379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26

US3312379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:26

US3312379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:26

US3312379

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:15

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:33

US3312379

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:26
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:55:33



**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:17:13
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:13
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:13
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	06 Nov 2020 00:17:13

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:17:17



US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:17:17

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:17:17

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	



**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:17:17

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:17
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:17:17

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:17:20
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:20
	(b) (4)	

US3312379

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:00:15**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:17:23
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:15

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:17:23
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:55:40
	(b) (4)	



**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:40
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:40
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	06 Nov 2020 00:55:40

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:55:44

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	



**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:55:44

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:55:44

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:55:44



US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:44
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:55:44

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:55:47
	(b) (4)	

US3312379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:47
	(b) (4)	

US3312379

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:00:15**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 00:55:52
	(b) (4)	

**US3312379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:00:15**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 00:55:52
	(b) (4)	

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:56

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '05 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:56



US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:15

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:56

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered 'UNBLND_DECIDE'	System	09 Mar 2021 23:57:56

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '05 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[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 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Amendment 5 (Amendment 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:15

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 11:43:44
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'CORRECT AS ENTERED. SUBJECT UNBLINDED UNDER AMENDMENT 5' (Site from System).	Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:46
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	09 Mar 2021 23:57:24
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24



**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:57:24

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Mar 2021 23:57:24

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:00:15**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered empty.	System	09 Mar 2021 23:57:24

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:10

US3312379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '05 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:10

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '10:07'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:10



**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '05 Mar 2021 10:07'	System	09 Mar 2021 23:58:10

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:00:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:21

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:00:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '05 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:21

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:00:15**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '10:06'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Mar 2021 23:58:21

**US3312379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:00:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:54
User entered '05 Mar 2021 10:06'	System	09 Mar 2021 23:58:21

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:00:15**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:25
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:58:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:03:08

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Neck strain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 01:05:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 01:05:53
Data point term sent to Coder	System	15 Sep 2020 01:05:00
User entered 'Neck Strain'	(b) (4), (b) (6)	15 Sep 2020 01:04:09



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
User entered empty.	System	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 00:29:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	06 Nov 2020 00:29:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Nov 2020 00:29:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 00:29:46
User entered '15 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 00:29:46
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 01:04:09



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
User entered empty.	System	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09



US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

US3312379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	06 Nov 2020 00:29:52
Data Entry Error	Karol Moore (b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
User entered '0'	System	15 Sep 2020 01:04:09



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25
User entered '1'	System	15 Sep 2020 01:04:09

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:25

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51

US3312379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:40:34
Data point term sent to Coder	System	07 Apr 2021 18:39:14
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 18:38:42
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 18:38:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: 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)	06 Nov 2020 00:31:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:31:28
Data point term sent to Coder	System	06 Nov 2020 00:30:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: 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)	06 Nov 2020 00:30:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:30:29
User closed query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-l, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' (Site from System).	System	06 Nov 2020 00:30:04
Query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-l, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' answered with 'updated' (Site from System).	Karol Moore (b) (4)	06 Nov 2020 00:30:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Nov 2020 00:29:47
User entered 'nasal CONGESTION' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 00:29:20
	(b) (4)	
User opened query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-I, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' (Site from System).	Coder Import (b) (4)	19 Oct 2020 07:41:28
	(b) (4)	
Data point term sent to Coder	System	18 Oct 2020 23:29:34
User entered 'congestion'	Karol Moore (b) (4)	18 Oct 2020 23:29:31
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered empty.	System	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	18 Oct 2020 23:29:48
User entered '21 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 23:29:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	18 Oct 2020 23:29:31
User entered 's ' (non-conformant).	System	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	18 Oct 2020 23:29:31
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered empty.	System	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31



US3312379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Oct 2020 23:29:48
User entered '1' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 23:29:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Oct 2020 23:29:31
User entered '0'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:29:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered '0'	System	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered '1'	System	18 Oct 2020 23:29:31

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:40:34
Data point term sent to Coder	System	07 Apr 2021 18:39:13
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 18:38:22
User entered 'GASTROENTERITIS' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	07 Apr 2021 18:38:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:32:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:32:32
Data point term sent to Coder	System	18 Oct 2020 23:31:34
User entered 'diarrhea'	Karol Moore (b) (4)	18 Oct 2020 23:30:37
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '11 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	18 Oct 2020 23:30:37
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered empty.	System	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '12 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	18 Oct 2020 23:30:37
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered empty.	System	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

US3312379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	



US3312379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

US3312379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'l'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

US3312379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:30:37
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered '0'	System	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered 'I'	System	18 Oct 2020 23:30:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:45:41
Data point term sent to Coder	System	07 Apr 2021 18:44:23
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 18:44:13
User entered 'GASTROENTERITIS' reason for change: Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:44:13
Data point term sent to Coder	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:33:33
Data point term sent to Coder	(b) (4)	
User entered 'diarrhea'	Coder Import (b) (4)	18 Oct 2020 23:33:33
	System	18 Oct 2020 23:32:35
	Karol Moore (b) (4)	18 Oct 2020 23:32:32
	(b) (4)	

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'No (N)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'No (N)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32



US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '15 Sep 2020'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32
	System	

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'No (N)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '19 Sep 2020'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32
	System	

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	18 Oct 2020 23:32:32



US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'No (N)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'None (NONE)'	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'I'	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	(b) (4)	18 Oct 2020 23:32:32



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered '0'	(b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	(b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	18 Oct 2020 23:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22
User entered empty.	Karol Moore (b) (4)	18 Oct 2020 23:32:32

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Apr 2021 18:39:22
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 23:32:32
	System	

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Apr 2021 18:39:22
User entered 'I'	Karol Moore (b) (4)	18 Oct 2020 23:32:32
	System	

US3312379

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:00:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:29
DataPoint activated with code reason code Data required.	Karol Moore (b) (4)	07 Apr 2021 18:43:57
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	07 Apr 2021 18:39:22

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site bruising, LLT: Injection site bruising - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:34:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 23:34:33
Data point term sent to Coder	System	18 Oct 2020 23:33:37
User entered 'bruising at injection site'	Karol Moore (b) (4)	18 Oct 2020 23:33:18
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '02 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	18 Oct 2020 23:33:18
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
User entered empty.	System	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
User entered empty.	System	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18



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Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Related (RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'None (NONE)'	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'l'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:00:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4)	18 Oct 2020 23:33:18
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
User entered '0'	System	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23
User entered '0'	System	18 Oct 2020 23:33:18

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:23

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #16 and 17 (SHORTNESS OF BREATH and DIFFICULTY BREATHING), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:37:56
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #16 and 17 (SHORTNESS OF BREATH and DIFFICULTY BREATHING), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:47:35
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #16 and 17 (SHORTNESS OF BREATH and DIFFICULTY BREATHING), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:48:02
User closed query 'Per DM CLR: Exacerbation AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:23:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchial conditions NEC, PT: Bronchiectasis, LLT: Bronchiectasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:15:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:15:18
Query 'Per DM CLR: Exacerbation AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4)	
' answered with 'BASELINE IS NOTED ON MH LINE 2' (Site from DM).	Karol Moore (b) (4)	23 Nov 2020 18:42:09
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	23 Nov 2020 18:42:05
	Karol Moore (b) (4)	23 Nov 2020 18:41:39
	(b) (4)	
User entered 'EXACERBATION OF bronchiectasis' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Nov 2020 18:41:39
User opened query 'Per DM CLR: Exacerbation AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:17:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Bronchiolitis, LLT: Bronchiolitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 00:44:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 00:44:38
Data point term sent to Coder	(b) (4)	
User entered 'EXACERBATION OF BRONCHIOLITIS'	System	11 Nov 2020 15:10:23
	(b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 15:30:35
User entered '30 Oct 2020'	Karol Moore (b) (4)	11 Nov 2020 15:10:00
	(b) (4), (b) (6)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
User entered empty.	System	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '08 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
User entered empty.	System	11 Nov 2020 15:10:00



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00



US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00



US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 indication is EXACERBATION OF BRONCHIOLITIS. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:38:02
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 indication is EXACERBATION OF BRONCHIOLITIS. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:48:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 indication is EXACERBATION OF BRONCHIOLITIS. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:48:13
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

US3312379

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
User entered '0'	System	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02
User entered 'I'	System	11 Nov 2020 15:10:00

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:02



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:42:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:42:46
Data point term sent to Coder	System	07 Apr 2021 18:41:18
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 18:40:24
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 18:40:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 17:32:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 17:32:46
Data point term sent to Coder	System	13 Nov 2020 17:31:55
User entered 'RUNNY NOSE'	(b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered empty.	System	13 Nov 2020 17:31:42



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 18:40:32
User entered '28 Oct 2020'	Karol Moore (b) (4)	13 Nov 2020 17:31:42
	(b) (4), (b) (6)	

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered empty.	System	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

US3312379

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:00:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Nov 2020 18:39:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 18:39:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 18:39:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:42
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:42

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered '0'	System	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered 'I'	System	13 Nov 2020 17:31:42

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #6 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:38:16
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #6 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:47:25
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #6 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:47:45
User closed query 'Per CDM re-query: Previous response noted, however Illness visit is prior to the onset of this AE. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:08:18
Query 'Per CDM re-query: Previous response noted, however Illness visit is prior to the onset of this AE. Please review and clarify or update accordingly. ' answered with 'THIS AE OCCURRED DURING THE CONVALESCENT PERIOD FOR ILLNESS VISIT #1 (START DATE 14SEP2020). NOT A NEW ILLNESS. THIS AE DIAGNOSIS ENCOMPASSES SYMPTOMS REPORTED ON SYMPTOM LOG.' (Site from DM).	Monica Atwood (b) (4) (b) (4)	21 Dec 2020 19:56:02

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Previous response noted, however Illness visit is prior to the onset of this AE. Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:02:24
User closed query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:02:24
Query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'CONFIRMED. SEE ILLNESS VISIT 2' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 17:00:58
User opened query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:56:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchial conditions NEC, PT: Bronchiectasis, LLT: Bronchiectasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:16:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:16:37
Data point term sent to Coder	System	13 Nov 2020 18:57:06
User entered 'exacerbation of bronchiectasis'	(b) (4), (b) (6)	13 Nov 2020 18:56:04

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04



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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

US3312379

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
User entered empty.	System	13 Nov 2020 18:56:04

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Please verify stop date. Corresponding medication has stop date of 23Sep2020. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:01:48
Query 'Please verify stop date. Corresponding medication has stop date of 23Sep2020. ' answered with 'AE SYMPTOMS DC'D ON 21SEP2020. HOWEVER, SUBJECT COMPLETED FULL ANITBIOTIC REGIMEN' (Site from CRA).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 17:07:13
User opened query 'Please verify stop date. Corresponding medication has stop date of 23Sep2020. ' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:52:45
User entered '21 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
User entered empty.	System	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:14:28
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' answered with 'REVIEWED AND UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:29:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:29:31
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:18:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04



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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

US3312379

Folder: Adverse Events

Form: Adverse Events (18)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04



US3312379

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:02:03
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'UPADTED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:45:25
User entered '0' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Nov 2020 18:45:18
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:19:10
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 18:56:04

US3312379

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	23 Nov 2020 18:45:18
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:56:04

US3312379

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
User entered '0'	System	13 Nov 2020 18:56:04

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21
User entered 'I'	System	13 Nov 2020 18:56:04



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:21

US3312379

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 17:33:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 17:33:56
Data point term sent to Coder	System	25 Jan 2021 17:33:30
User entered 'right ovarian cyst'	(b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 17:33:24



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

US3312379

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

US3312379

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

US3312379

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

US3312379

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:00:15

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #23 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:17:49
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #23 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:41:42
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:41:35
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #23 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:48:23
User entered '1'	(b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:41:35
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 17:33:24

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:26:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
User entered	(b) (4)	15 Apr 2021 15:16:16
'USA-US300-2021-mRNA-1273-P301000023'	System	15 Apr 2021 15:16:16
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 15:16:16

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If subject has a medical history of endometriosis was the SAE considered a worsening of the endometriosis? If so, please consider updating event term as such.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:26:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
Query 'PV Query: If subject has a medical history of endometriosis was the SAE considered a worsening of the endometriosis? If so, please consider updating event term as such.' answered with 'noted as history in narrative relative to this SAE, was diagnosed Jan18 2021, already an AE, data was changed to make severe.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:50:05
User opened query 'PV Query: If subject has a medical history of endometriosis was the SAE considered a worsening of the endometriosis? If so, please consider updating event term as such.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:46:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 19:30:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 19:30:55
Data point term sent to Coder	System	10 Mar 2021 19:15:03
User entered 'endometriosis'	(b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55



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Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 19:14:55

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Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:32:54
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'PENIDNG OUTCOME. CONFIRMED STILL ONGOING.' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 20:42:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:48:13
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 19:14:55

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:47:49
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 19:14:55

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55



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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 17:00:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:33:03
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)	03 May 2021 18:32:59
Query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'SUBMITTED 26APR21' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 21:25:24
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 'CONFIRMED PCR COVID-19 TEST NEGATIVE.' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 21:25:06
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User opened query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:47:20
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)	23 Apr 2021 12:46:50

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
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) (4), (b) (6)	15 Apr 2021 05:48:15
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 'entered' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 19:48:14
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	14 Apr 2021 19:47:11
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered '11 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Form: Adverse Events (20)**

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered '13 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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**Form: Adverse Events (20)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55



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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:11
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:47:11
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:14:55

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Deviated septum was reported in medical history. Please clarify if this was a deviated nasal septum. If so, kindly update in the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:26:12
User closed query 'PV Query: Per the case narrative the subject has a history of endometriosis. Please add to the medical history in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:26:10
User closed query 'PV Query: Per the case narrative the subject has a history of ovarian cysts. Please add to the medical history in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:26:07
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:06:20

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[Narrative](#)

Audit	User	Time (GMT)
User entered '28 Y/O WITH HISTORY OF OVARIAN CYSTS, ENDOMETRIOSIS, AND RECENT RIGHT OVARIAN CYSTECTOMY (17MAR2021) DEVELOPED SEVERE PELVIC PAIN REQUIRING HOSPITALIZATION DURING WHICH PAIN CONTROLLED WITH HYDROCODONE/APAP 5/325 AND IBUPROFEN 800MG. AVIANE OCP'S ALSO INITIATED DURING HOSPITALIZATION. SUBJECT'S PAIN IS IMPROVED BUT NOT RESOLVED. SHE CONTINUES TO USE MEDICATION AND HAS A FOLLOW-UP APPOINTMENT WITH HER PHYSICIAN IN 2 WEEKS. WILL FOLLOW AND REQUEST MED RECORDS FOR THIS SAE, NOT RELATED TO IP, NOT RELATED TO COVID INFECTION Follow up 21Apr21 developed severe pelvic pain requiring hospitalization during which pain was controlled initially with with iv morphine then alternating hydrocodone/APAP 5/325 and toradol q 3 hours. Loestrin was reinitiated during hospitalization, as subject had recently discontinued it as part of her family planning. Loperamide was given for an irritable bowel syndrome diarrhea flare up that did not prolong hospitalization. An ultrasound showed increased complexity and size of a right ovarian mass that was probably post op related fluid from previous cystectomy; Gynecology service was not concerned for torsion or abscess. The cause of the pain was considered to be endometriosis. Metabolic profile, cbc, and ua were normal. She was discharged on hydrocodone/apap and ibuprofen for pain. Abdominal pain and diarrhea persist. Since discharge she has followed up with PCP and Gynecology and is now also using vaginal diazepam and doing pelvic floor physical therapy to control pain. Further workup and visit with gastroenterology are scheduled for eval of diarrhea. Rifaximin, which subject was taking for IBS/diarrhea since before this event, was discontinued. Will continue to follow until her conditions return to baseline.' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:06:20

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per the case narrative the subject has a history of ovarian cysts. Please add to the medical history in the eCRF.' answered with 'ovarian cyst present in Medical history' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:01:25
Query 'PV Query: Deviated septum was reported in medical history. Please clarify if this was a deviated nasal septum. If so, kindly update in the medical history eCRF.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:01:10
Query 'PV Query: Per the case narrative the subject has a history of endometriosis. Please add to the medical history in the eCRF.' answered with 'noted as history in narrative relative to this SAE, was diagnosed Jan18 2021, already an AE, data was changed to make severe.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:49:54
User opened query 'PV Query: Deviated septum was reported in medical history. Please clarify if this was a deviated nasal septum. If so, kindly update in the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:48:40
User opened query 'PV Query: Per the case narrative the subject has a history of endometriosis. Please add to the medical history in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:45:50
User opened query 'PV Query: Per the case narrative the subject has a history of ovarian cysts. Please add to the medical history in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:45:30
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:47:50

US3312379

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '28 y/o with history of ovarian cysts, endometriosis, and recent right ovarian cystectomy (17Mar2021) developed severe pelvic pain requiring hospitalization during which pain controlled with hydrocodone/APAP 5/325 and ibuprofen 800mg. Aviane OCP's also initiated during hospitalization. Subject's pain is improved but not resolved. She continues to use medication and has a follow-up appointment with her physician in 2 weeks. Will follow and request med records for this SAE, not related to IP, not related to Covid infection' reason for change: Data Entry Error User signature succeeded.	(b) (4), (b) (6) (b) (4)	14 Apr 2021 19:47:50
	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4), (b) (6) (b) (4)	10 Mar 2021 19:14:55



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 19:47:11
User entered '0'	System	10 Mar 2021 19:14:55

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 19:14:55

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37

US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 19:17:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 19:17:55
Data point term sent to Coder	System	10 Mar 2021 19:17:06
User entered 'urinary tract infection'	(b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered empty.	System	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered empty.	System	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

US3312379

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 17:00:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'l'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered '0'	System	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered 'I'	System	10 Mar 2021 19:16:41

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:28
User entered 'USA-US300-2021-mRNA-1273-P301000020'	System	24 Mar 2021 15:55:07
User entered 'New'	(b) (4), (b) (6)	24 Mar 2021 15:55:07

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Carlos Fierro (b) (4)	13 Apr 2021 01:41:38 09 Apr 2021 15:59:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:39:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:39:25
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'updated' (Site from Safety).	Monica Atwood (b) (4)	09 Apr 2021 14:31:34
Data point term sent to Coder	System	09 Apr 2021 14:31:30
Coding entries removed.	Monica Atwood (b) (4)	09 Apr 2021 14:30:53
User entered 'RIGHT OVARIAN CYST' reason for change: Data Entry Error	Monica Atwood (b) (4)	09 Apr 2021 14:30:53
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvis and broad ligament disorders NEC, PT: Adnexa uteri pain, LLT: Ovarian pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:19:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:19:26
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:12:19
Data point term sent to Coder	System	23 Mar 2021 21:53:06
User entered 'right ovarian cyst pain'	(b) (4), (b) (6)	23 Mar 2021 21:52:06



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (18-JAN-2021). If not updating the start date, please clarify. ' (Site from Safety). Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (18-JAN-2021). If not updating the start date, please clarify. ' answered with 'NA. SUBJECT HAD 2 SEPARATE EVENTS OF RIGHT OVARIAN CYSTS. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:35:17
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (18-JAN-2021). If not updating the start date, please clarify. ' (Site from Safety).	Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:29:36
User signature succeeded.	(b) (4), (b) (6)	15 Apr 2021 21:05:48
User entered '13 Mar 2021'	Carlos Fierro (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 15:59:18 23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06



**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 01:41:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'NO RESULTS AVAILABLE AT THIS TIME, AWAITING MEDICAL RECORDS' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:59:18
User entered '1' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:56:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:50:26
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:12:56
	(b) (4), (b) (6)	23 Mar 2021 21:52:06

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User closed query 'PV Query: please clarify event end date/outcome as it was reported that subject still had pain but "below levels associated with this problem"; does subject have history of chronic pain? If so, please add to CRF ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 01:41:47
	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
Query 'PV Query: please clarify event end date/outcome as it was reported that subject still had pain but "below levels associated with this problem"; does subject have history of chronic pain? If so, please add to CRF ' answered with 'updated, removed pain from event term' (Site from Safety).	Monica Atwood (b) (4)	09 Apr 2021 14:32:44
	(b) (4)	
User opened query 'PV Query: please clarify event end date/outcome as it was reported that subject still had pain but "below levels associated with this problem"; does subject have history of chronic pain? If so, please add to CRF ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:12:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:52:06

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:41:58
User closed query 'PV Query: Please confirm if right ovarian cyst is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If right ovarian cyst is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 01:41:56
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)	13 Apr 2021 01:41:53
User closed query 'PV Query: Did the subject have a medical history of right ovarian cyst? Was the SAE considered a worsening of the subject's medical history of right ovarian cyst? ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 01:41:49
User closed query 'Per DM CLR: Narrative = RIGHT OVARIAN CYSTECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:29:32
User closed query 'Per DM CLR: Narrative = TAKING AVIANE OCP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:14:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
Query 'Per DM CLR: Narrative = TAKING AVIANE OCP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'cm page updated' (Site from DM).	Monica Atwood (b) (4)	09 Apr 2021 14:50:49
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 'unknown medical records pending' (Site from Safety).	Monica Atwood (b) (4)	09 Apr 2021 14:50:30

US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = RIGHT OVARIAN CYSTECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'See Con Procedure line #2 Right ovarian cystectomy' (Site from DM).	Monica Atwood (b) (4)	09 Apr 2021 14:39:00
Query 'PV Query: Please confirm if right ovarian cyst is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If right ovarian cyst is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' answered with 'AE event term updated' (Site from Safety).	Monica Atwood (b) (4)	09 Apr 2021 14:34:16
Query 'PV Query: Did the subject have a medical history of right ovarian cyst? Was the SAE considered a worsening of the subject's medical history of right ovarian cyst? ' answered with 'not medical history but previous AE of right ovarian cyst 18Jan2021' (Site from Safety).	Monica Atwood (b) (4)	09 Apr 2021 14:33:49
User opened query 'Per DM CLR: Narrative = TAKING AVIANE OCP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:55:10
User opened query 'Per DM CLR: Narrative = RIGHT OVARIAN CYSTECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:55:05
User opened query 'PV Query: Please confirm if right ovarian cyst is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If right ovarian cyst is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:13:09
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)	02 Apr 2021 22:12:29



US3312379

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 17:00:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have a medical history of right ovarian cyst? Was the SAE considered a worsening of the subject's medical history of right ovarian cyst? ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:12:11
User entered '28 year old woman with history of right ovarian cyst developed right ovarian cyst pain on 13Mar21 that required ER visit. Subject discharged from ER 14Mar21 on Tylenol, Ibuprofen, and Oxycodone. Subject returned to ER on 16Mar21 with poorly controlled pain and was admitted. Right ovarian cystectomy with ovarian preservation was performed on 17Mar21. Subject is recovering well, but still has pain. She is able to complete ADL's without assistance but has not yet returned to work. She has been taking Aviane OCP's, Tylenol, Ibuprofen, and Oxycodone for pain but did not require pain meds today. Will procure med records and will follow. Because pain today has returned to levels below previously associated with this problem, will close SAE'	(b) (4), (b) (6)	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 21:52:06

**US3312379**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 21:52:06

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:00:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:02
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:48
User closed query 'Per ETRTR: According to SAE page "Right Ovarian Cyst Pain", medication was given for SAE, but the same is missing in this folder (medication present with Start date on 18Jan21, but missing medications for event on March2021). Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:05:01
Query 'Per ETRTR: According to SAE page "Right Ovarian Cyst Pain", medication was given for SAE, but the same is missing in this folder (medication present with Start date on 18Jan21, but missing medications for event on March2021). Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'ADDED ON CONMED PAGES' (Site from CRA).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 14:27:16
User opened query 'Per ETRTR: According to SAE page "Right Ovarian Cyst Pain", medication was given for SAE, but the same is missing in this folder (medication present with Start date on 18Jan21, but missing medications for event on March2021). Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:59:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:00:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 15:03:38
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 Sep 2020 15:03:38
Data point term sent to Coder	System	09 Sep 2020 15:02:29
User entered 'mirena'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'birth control'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'device'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'every 5 years'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'intrauterine'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'un Jan 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:22:00
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:22:00
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User entered empty.	System	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User entered empty.	System	09 Sep 2020 15:01:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:19
User entered empty.	System	09 Sep 2020 15:01:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 15:03:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:03:38
Data point term sent to Coder	System	09 Sep 2020 15:02:28
User entered 'setraline'	Karol Moore (b) (4)	09 Sep 2020 15:02:20



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'depression'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '150'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'un Jan 2020'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:02:20
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:02:20

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:02:20



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 15:02:20

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 15:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 15:22:52
Data point term sent to Coder	System	09 Sep 2020 15:05:33
User entered 'azithromycin'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:04:56

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'chronic ideopathic bronchiectasis'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '500'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'other (OTHER)'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'three times a week'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'un Jul 2016'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:04:56
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Please note, '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 started before vaccination. Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:55:55
Query 'Per DM CLR: Please note, '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 started before vaccination. Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:16:29
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:16:23
User opened query 'Per DM CLR: Please note, '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 started before vaccination. Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:48:27
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 01:06:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 01:06:32



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 01:06:32
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 15:04:56
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:04:56

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:04:56

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:04:56

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:04:56

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: CETRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:07:47
Data point term sent to Coder User entered 'cetirizine'	System Karol Moore (b) (4)	09 Sep 2020 15:06:35 09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:56:47
' (Site from DM).		
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:18:09
' answered with 'seasonal allergies were update per source.' (Site from DM).		
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4), (b) (6)	16 Oct 2020 13:48:45
' (Site from DM).		
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '10'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4)	09 Sep 2020 15:05:45
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'un UNK 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:24:51
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:24:51
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User entered '1'	System	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User entered '1'	System	09 Sep 2020 15:05:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:23
User entered '804 (804)'	System	09 Sep 2020 15:05:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 15:25:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 15:25:48
Data point term sent to Coder	System	09 Sep 2020 15:07:38
User entered 'trazodone'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:07:34

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'sleep difficulty'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '50'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'un UNK 2016'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:07:34
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:07:34

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:07:34

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:07:34



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:09:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:09:45
Data point term sent to Coder User entered 'montelukast'	System Karol Moore (b) (4)	09 Sep 2020 15:08:47 09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:57:05
' (Site from DM).		
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:18:18
' answered with 'seasonal allergies were update per source.' (Site from DM).		
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4), (b) (6)	16 Oct 2020 13:49:40
' (Site from DM).		
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '10'	Karol Moore (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'un Apr 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:25:25
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:25:25
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User entered '1'	System	09 Sep 2020 15:08:08



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User entered '1'	System	09 Sep 2020 15:08:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
User entered '804 (804)'	System	09 Sep 2020 15:08:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ELETRIPTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 16:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:14:44
Data point term sent to Coder	System	09 Sep 2020 15:12:59
User entered 'eletriptan'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:12:10

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'migraine headaches'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'un UNK 2019'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:12:10
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:12:10

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:12:10

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:12:10

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 16:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:14:44
Data point term sent to Coder	System	09 Sep 2020 15:15:05
User entered 'cyanocobalmin'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:14:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'pernicious anemia'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query ' Per DM CLR: Please provide the actual dose for this medication instead of number of injections as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:15:26
' (Site from DM). Query ' Per DM CLR: Please provide the actual dose for this medication instead of number of injections as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:26:30
' answered with 'updated' (Site from DM). User entered '1000' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:26:22
User opened query ' Per DM CLR: Please provide the actual dose for this medication instead of number of injections as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	(b) (4), (b) (6)	16 Oct 2020 13:52:21
' (Site from DM). User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:14:08



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Karol Moore (b) (4)	25 Oct 2020 21:26:22
	(b) (4)	
User entered 'Other (OTHER)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	25 Oct 2020 21:26:22
	(b) (4)	
User entered 'injection'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'every month (QM)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query "'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of PERNICIOUS ANEMIA. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 13:57:44
' (Site from DM). Query "'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of PERNICIOUS ANEMIA. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:31:43
' answered with 'updated start date' (Site from DM). User entered 'UN UNK 2009' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	06 Nov 2020 00:31:30
User opened query "'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of PERNICIOUS ANEMIA. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.	(b) (4), (b) (6)	16 Oct 2020 13:52:00
' (Site from DM). User entered 'un UNK 2008'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:14:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:14:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:14:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:14:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	09 Sep 2020 15:14:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:17:49
Data point term sent to Coder User entered 'ergocalciferol'	System Karol Moore (b) (4)	09 Sep 2020 15:17:14 09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4)	09 Sep 2020 15:17:02
	Karol Moore (b) (4)	
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'vitamin d deficiency'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '50000'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'units'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'every week (QS)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'un Dec 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:17:02

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Dec 2020 16:27:39
User entered 'Yes (Y)'	Monica Atwood (b) (4)	09 Sep 2020 15:17:02
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Dec 2020 16:27:39
User entered empty.	Monica Atwood (b) (4)	09 Sep 2020 15:17:02
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:28:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 15:28:06
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	09 Sep 2020 15:28:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:17:02
User entered empty.	System	09 Sep 2020 15:17:02
	Karol Moore (b) (4)	09 Sep 2020 15:17:02
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User entered '1'	System	09 Sep 2020 15:17:02

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User entered '1'	System	09 Sep 2020 15:17:02

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:30
User entered '803 (803)'	System	09 Sep 2020 15:17:02



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: MUCOLYTICS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: HYPERTONIC SALINE SOLUTION - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:17:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:17:16
Data point term sent to Coder	System	13 Nov 2020 15:28:04
Data point term sent to Coder	System	26 Oct 2020 11:57:03
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	26 Oct 2020 11:56:47
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 'HyperSal (hypersaline solution) is a hypertonic saline solution (sodium chloride). ' (Site from System).	Heather Barker (b) (4)	26 Oct 2020 11:56:47
User entered 'HYPERSALINE solution 7.0%' reason for change: Data Entry Error	Heather Barker (b) (4)	26 Oct 2020 11:56:40
Data point term sent to Coder	System	18 Oct 2020 23:20:28
User entered 'HYPERSALINE 7.0%' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 23:19:47

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

[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)	25 Sep 2020 14:14:42
Data point term sent to Coder	System	09 Sep 2020 15:19:18
User entered 'hypersaline 0.7%'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Bronchietasis is not listed as medical history. Please verify if condition should be CHRONIC IDEOPATHIC BRONCHIECTASIS and update if needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:44
Query 'Bronchietasis is not listed as medical history. Please verify if condition should be CHRONIC IDEOPATHIC BRONCHIECTASIS and update if needed. ' answered with 'updated' (Site from CRA).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:27:16
User entered 'chronic ideopathic BRONCHIETASIS' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:27:09
User opened query 'Bronchietasis is not listed as medical history. Please verify if condition should be CHRONIC IDEOPATHIC BRONCHIECTASIS and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:46:47
User entered 'bronchietasis'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:19:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Other (OTHER)'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'nebulizer' reason for change: Data Entry Error	Karol Moore (b) (4)	09 Sep 2020 15:28:24
	(b) (4)	
User entered 'unit'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'un UNK 2015'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Sep 2020 15:19:08
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:19:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:19:08

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:19:08

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:26:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:26:45
Data point term sent to Coder User entered 'acetaminophen'	System Karol Moore (b) (4)	09 Sep 2020 15:25:38 09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'headache'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '1000'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:57:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'correct as entered. subject recorded taking medication in ediary in diary dose 1' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:21:23

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:53:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User entered empty.	System	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User entered empty.	System	09 Sep 2020 15:25:18

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:33
User entered empty.	System	09 Sep 2020 15:25:18

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:29:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 15:29:39
Data point term sent to Coder User entered 'acetaminophen'	System Karol Moore (b) (4)	09 Sep 2020 15:28:47 09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	09 Sep 2020 15:27:53



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'headache'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '1000'	Karol Moore (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4)	09 Sep 2020 15:27:53



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:57:40
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:21:31
' answered with 'correct as entered. subject recorded taking medication in ediary in diary dose 1' (Site from DM).		

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:53:50
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User entered empty.	System	09 Sep 2020 15:27:53

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User entered empty.	System	09 Sep 2020 15:27:53



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:36
User entered empty.	System	09 Sep 2020 15:27:53

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:21:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:21:34
Data point term sent to Coder	System	15 Sep 2020 01:06:01
User entered 'methylprednisolone'	(b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'neck strain'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '24'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:05:40



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User entered '1'	System	15 Sep 2020 01:05:40

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User entered '1'	System	15 Sep 2020 01:05:40

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:40
User entered '804 (804)'	System	15 Sep 2020 01:05:40

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:21:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:21:34
Data point term sent to Coder	System	15 Sep 2020 01:09:03
User entered 'methylprednisolone'	(b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'neck strain'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '20'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User entered '1'	System	15 Sep 2020 01:08:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User entered '1'	System	15 Sep 2020 01:08:07

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:46
User entered '804 (804)'	System	15 Sep 2020 01:08:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:44:49
Data point term sent to Coder	System	15 Sep 2020 21:31:12
User entered 'ibuprofen'	(b) (4), (b) (6)	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Neck Strain'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '800'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' (Site from CRA). Query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:18
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:27:53
User opened query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:49:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 15:27:49
User entered empty.	Karol Moore (b) (4)	15 Sep 2020 21:30:45
	(b) (4)	
	(b) (4), (b) (6)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User entered empty.	System	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User entered empty.	System	15 Sep 2020 21:30:45

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:50
User entered empty.	System	15 Sep 2020 21:30:45

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:40:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:40:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:12:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:12:53
Data point term sent to Coder	System	18 Oct 2020 23:25:30
User entered 'augmentin amoxicillin 875mg/potassium clavulanate125mg'	Karol Moore (b) (4)	18 Oct 2020 23:24:46
	(b) (4)	



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query "This indication is not listed on Medical history page or AE log for these dates. Please verify if indication should be added to Medical History page or AE log and update as needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:53:23
Query "This indication is not listed on Medical history page or AE log for these dates. Please verify if indication should be added to Medical History page or AE log and update as needed. ' answered with 'AE LISTED ON LINE 9 OF AE PAGE' (Site from CRA).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:28:55
User opened query "This indication is not listed on Medical history page or AE log for these dates. Please verify if indication should be added to Medical History page or AE log and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:51:53
User entered 'bronchiectasis exacerbation'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'tablet (TABLET)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	18 Oct 2020 23:24:46



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4)	18 Oct 2020 23:24:46
	Karol Moore (b) (4)	
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User entered '2'	System	18 Oct 2020 23:24:46

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User entered '1'	System	18 Oct 2020 23:24:46



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:53
User entered '804 (804)'	System	18 Oct 2020 23:24:46

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 23:26:30
Data point term sent to Coder	System	18 Oct 2020 23:25:31
User entered 'acetaminophen'	Karol Moore (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:58:31
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Kelly Moen (b) (4) (b) (4)	30 Nov 2020 22:38:11
' answered with 'adverse reaction of headache did not meet AE reporting criteria' (Site from DM).		

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:22:59
User entered 'headache'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '500'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '26 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '27 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User entered empty.	System	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User entered empty.	System	18 Oct 2020 23:25:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:56
User entered empty.	System	18 Oct 2020 23:25:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
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)	18 Oct 2020 23:27:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 23:27:31
Data point term sent to Coder	System	18 Oct 2020 23:26:31
User entered 'seasonal influenza vaccination'	Karol Moore (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'influenza prophylaxis'	Karol Moore (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'I'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 23:26:24



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Other (OTHER)'	Karol Moore (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'injection'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User entered empty.	System	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User entered empty.	System	18 Oct 2020 23:26:24

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:00
User entered empty.	System	18 Oct 2020 23:26:24

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 19:32:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 19:32:33
Data point term sent to Coder	System	07 Apr 2021 19:32:23
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 19:32:11
User signature succeeded.	(b) (4)	
	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:51:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:51:33
Data point term sent to Coder	System	11 Nov 2020 14:50:54
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:36:23
Signature has been broken.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:32:11
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:32:11
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'FEVER'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '500'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' (Site from CRA). Query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:54:31
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:25:37
User opened query 'Per AE log this indication has a stop date. Please verify if medication should be ongoing and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:52:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 15:25:30
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 14:50:03
	(b) (4)	
	(b) (4), (b) (6)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User entered empty.	System	11 Nov 2020 14:50:03

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User entered empty.	System	11 Nov 2020 14:50:03

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:00:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:03
User entered empty.	System	11 Nov 2020 14:50:03



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:59:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:59:42
Data point term sent to Coder Coding entries removed.	System Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:49:43 07 Apr 2021 18:49:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:40:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:40:54

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:19:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:19:36
Data point term sent to Coder	System	11 Nov 2020 14:55:02
User entered 'AUGMENTIN AMOXICILLIN 875MG/POTASSIUM CLAVULANATE125MG'	(b) (4), (b) (6)	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:06:44
Signature has been broken.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 18:49:16
User entered 'EXACERBATION OF BRONCHIECTASIS' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:49:16
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'EXACERBATION OF Bronchiolitis'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Per AE log this indication has start date of 30Oct2020. Please verify AE and medication start date and update as needed. ' (Site from CRA).	(b) (4)	
Query 'Per AE log this indication has start date of 30Oct2020. Please verify AE and medication start date and update as needed. ' answered with 'UPDATED AE LOG' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:55:47
Query 'Per AE log this indication has start date of 30Oct2020. Please verify AE and medication start date and update as needed. ' answered with 'UPDATED AE LOG' (Site from CRA).	Karol Moore (b) (4)	13 Nov 2020 15:30:13
User opened query 'Per AE log this indication has start date of 30Oct2020. Please verify AE and medication start date and update as needed. ' (Site from CRA).	(b) (4)	
User opened query 'Per AE log this indication has start date of 30Oct2020. Please verify AE and medication start date and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:54:58
User entered '29 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '08 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:54:59



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User entered '2'	System	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User entered '1'	System	11 Nov 2020 14:54:59

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:06
User entered '804 (804)'	System	11 Nov 2020 14:54:59

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
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 corresponding AE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:38:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if corresponding AE should be recorded, and update con med indication or provide clarification. ' answered with 'CONFIRMED SUBJECT DENIES WORSENING OF CONDITION' (Site from DM).	(b) (4) Karol Moore (b) (4)	07 Apr 2021 14:26:02
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 corresponding AE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:48:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:30:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:30:51
Data point term sent to Coder	System	04 Dec 2020 18:03:12
User entered 'hydrocodone 5 mg/ acetaminophen 325 mg'	(b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Torn Right meniscus'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:03:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 18:02:51



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	04 Dec 2020 18:03:10
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 18:03:10
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Dec 2020 18:02:51
User entered '19 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User entered empty.	System	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User entered empty.	System	04 Dec 2020 18:02:51

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:10
User entered empty.	System	04 Dec 2020 18:02:51

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Dec 2020 17:27:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:27:39
Data point term sent to Coder	System	23 Dec 2020 16:30:46
User entered 'NATURE MADE MULTIVITAMIN'	Monica Atwood (b) (4) (b) (4)	23 Dec 2020 16:30:27

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'HEALTH MAINTENANCE'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '1'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'tablet (TABLET)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'once daily (QD)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Oral (ORAL)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '22 Nov 2020'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered '0'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	23 Dec 2020 16:30:27
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Dec 2020 16:30:27

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Dec 2020 16:30:27

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Dec 2020 16:30:27

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
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)	25 Jan 2021 17:31:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 17:31:48
Data point term sent to Coder	System	25 Jan 2021 17:31:27
User entered 'hydrocodone/acetaminophen'	(b) (4), (b) (6)	25 Jan 2021 17:31:14



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Right ovarian cyst'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '5/325'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	Karol Moore (b) (4)	16 Apr 2021 19:23:00
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	16 Apr 2021 19:23:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	Karol Moore (b) (4)	16 Apr 2021 19:23:00
User entered '22 Jan 2021' reason for change: Data Entry Error	Karol Moore (b) (4)	16 Apr 2021 19:23:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User entered empty.	System	25 Jan 2021 17:31:14

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User entered empty.	System	25 Jan 2021 17:31:14



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:13
User entered empty.	System	25 Jan 2021 17:31:14

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:17:08
Data point term sent to Coder	System	05 Feb 2021 15:55:38
User entered 'doxycycline'	(b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Feb 2021 15:54:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 15:54:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:54:58
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 15:54:52
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'chronic idiopathic bronchiectasis'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '100'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4)	16 Apr 2021 19:23:12
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	16 Apr 2021 19:23:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:12
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:12
User signature succeeded.	(b) (4) Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:54:52



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User entered '1'	System	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User entered '1'	System	05 Feb 2021 15:54:52

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:22
User entered '804 (804)'	System	05 Feb 2021 15:54:52

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFPODOXIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:28:50
Data point term sent to Coder	System	10 Mar 2021 19:09:52
User entered 'cefpodoxime'	(b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'urinary tract infection'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '100'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User entered '2'	System	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User entered '1'	System	10 Mar 2021 19:09:42

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:26
User entered '804 (804)'	System	10 Mar 2021 19:09:42

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 17:16:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 17:16:45
Data point term sent to Coder	System	02 Apr 2021 17:15:59
User entered 'acetaminophen'	(b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'right ovarian cyst pain'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '1000'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '14 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:27
User signature succeeded.	(b) (4) Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:27
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:27
User signature succeeded.	(b) (4) Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User entered empty.	System	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User entered empty.	System	02 Apr 2021 17:15:30

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:34
User entered empty.	System	02 Apr 2021 17:15:30

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:11:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Apr 2021 12:11:12
Data point term sent to Coder	System	02 Apr 2021 17:16:59
User entered 'ibuprofen'	(b) (4), (b) (6)	02 Apr 2021 17:16:16



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'right ovarian cyst pain'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '400'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '14 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:37
User signature succeeded.	(b) (4) Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:37
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	16 Apr 2021 19:23:37
User signature succeeded.	(b) (4) Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered empty.	System	02 Apr 2021 17:16:16

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered empty.	System	02 Apr 2021 17:16:16



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered empty.	System	02 Apr 2021 17:16:16

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:00:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:29:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:29:06
Data point term sent to Coder	System	02 Apr 2021 17:18:00
User entered 'oxycodone'	(b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'right ovarian cyst pain'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '5'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '14 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:00:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4)	16 Apr 2021 19:23:53
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	16 Apr 2021 19:23:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 17:17:11

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:00:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
Signature has been broken.	(b) (4)	16 Apr 2021 19:23:53
User entered '23 Mar 2021' reason for change: Data Entry Error	Karol Moore (b) (4)	16 Apr 2021 19:23:53
User signature succeeded.	(b) (4)	07 Apr 2021 18:10:03
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 17:17:11

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:17:11



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User entered empty.	System	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User entered empty.	System	02 Apr 2021 17:17:11

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:41
User entered empty.	System	02 Apr 2021 17:17:11

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 15:01:44
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 Apr 2021 15:01:44
Data point term sent to Coder	System	09 Apr 2021 14:52:09
User entered 'METOPROLOL'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:52:06

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'TACHYCARDIA'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '25'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'mg (mg)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:00:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'once daily (QD)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'Oral (ORAL)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '07 Apr 2021'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '0'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	09 Apr 2021 14:52:06
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:52:06

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:52:06

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 14:52:06

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: AVIANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:51:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:51:58
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:59:18
Data point term sent to Coder	System	09 Apr 2021 14:53:10
User entered 'AVIANE (LEVONORGESTREL/ETHINYL ESTRADIOL)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 14:53:05

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'BIRTH CONTROL'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '1'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'tablet (TABLET)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'once daily (QD)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'Oral (ORAL)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '17 Mar 2021'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered '0'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:00:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:18
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	09 Apr 2021 14:53:05
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:53:05

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:53:05

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 14:53:05

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 19:27:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 19:27:00
Data point term sent to Coder	System	16 Apr 2021 19:25:15
User entered 'IBUPROFEN'	Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:24:33



US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'ENDOMETRIOSIS'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '800'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '11 Apr 2021'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:24:33
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:24:33

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:24:33



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:24:33

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
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)	16 Apr 2021 19:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 19:27:01
Data point term sent to Coder User entered	System	16 Apr 2021 19:26:16
'HYDROCODONE/ACETAMINOPHEN'	Karol Moore (b) (4)	16 Apr 2021 19:25:35

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'ENDOMETROSIS'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '5/325'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '11 Apr 2021'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:25:35
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:25:35

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:25:35

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:25:35

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:00:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: LOPAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 19:29:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 19:29:23
Data point term sent to Coder User entered 'LOPAMIDE'	System Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:28:20 16 Apr 2021 19:28:07

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:00:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'ENDOMETRIOSIS'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '2'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

US3312379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:00:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	



US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

US3312379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '11 Apr 2021'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	



**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Apr 2021 19:28:07
	(b) (4)	

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:28:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:28:07

**US3312379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:00:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:28:07

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:00:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:02
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:48
User closed query 'Per ETRTR: According to SAE narrative, "RIGHT OVARIAN CYSTECTOMY WITH OVARIAN PRESERVATION WAS PERFORMED ON 17MAR21", but the same is missing in this folder. Please update this folder as applicable. Also go to SAE page and tick on "Concomitant Procedures" action taken since procedure was completed for SAE, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:05:15
Query 'Per ETRTR: According to SAE narrative, "RIGHT OVARIAN CYSTECTOMY WITH OVARIAN PRESERVATION WAS PERFORMED ON 17MAR21", but the same is missing in this folder. Please update this folder as applicable. Also go to SAE page and tick on "Concomitant Procedures" action taken since procedure was completed for SAE, thanks.' answered with 'ADDED AND UPDATED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:22:50
User opened query 'Per ETRTR: According to SAE narrative, "RIGHT OVARIAN CYSTECTOMY WITH OVARIAN PRESERVATION WAS PERFORMED ON 17MAR21", but the same is missing in this folder. Please update this folder as applicable. Also go to SAE page and tick on "Concomitant Procedures" action taken since procedure was completed for SAE, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 18:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 17:55:28

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered '19 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 17:56:05

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered 'Right MENISCUS REPAIR' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 17:56:22
User entered 'meniscus repair'	(b) (4), (b) (6)	04 Dec 2020 17:56:05



**US3312379**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:56:05

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 17:56:05

**US3312379**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:00:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:06:44
User entered '17 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:22:42

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:06:44
User entered 'RIGHT OVARIAN CYSTECTOMY'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:22:42

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:06:44
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:22:42

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:06:44
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 18:22:42

**US3312379**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:00:15**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:53
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered '18 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:28:41

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:00:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:53
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered 'RIGHT OVARIAN CYSTECTOMY'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:28:41



US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:00:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:53
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:28:41

US3312379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:00:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:58:53
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:46:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	16 Apr 2021 19:28:41

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'USA-US300-2021-MRNA-1273-P301000020'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Carlos'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Fierro'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '16300 College Blvd'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Shawnee'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'KS'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '66219'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:45:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'US'	(b) (4) System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Apr 2021 20:03:34
User entered '2'	System	08 Apr 2021 14:45:27
User entered '1'	System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'USA-US300-2021-MRNA-1273-P301000020'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Carlos'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Fierro'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '16300 College Blvd'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Shawnee'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'KS'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '66219'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:45:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'US'	(b) (4) System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Apr 2021 20:03:34
User entered '2'	System	08 Apr 2021 14:45:27
User entered '1'	System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '24/Mar/2021 08:57'	(b) (4) System	24 Mar 2021 15:57:12

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:15

**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)	26 Apr 2021 19:40:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:45:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:57:12
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:57:01

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'USA-US300-2021-MRNA-1273-P301000020'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Carlos'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Fierro'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '16300 College Blvd'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Shawnee'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'KS'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '66219'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:45:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'US'	(b) (4) System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Apr 2021 20:03:34
User entered '2'	System	08 Apr 2021 14:45:27
User entered '1'	System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:59
User entered '08/Apr/2021 10:45'	(b) (4) System	08 Apr 2021 14:45:27

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:15

**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)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:45:27

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'USA-US300-2021-MRNA-1273-P301000020'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Yes (Y)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'No (N)'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Carlos'	System	24 Mar 2021 15:55:07

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Fierro'	System	24 Mar 2021 15:55:07



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '16300 College Blvd'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'Shawnee'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered 'KS'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:56:54
User entered '66219'	System	24 Mar 2021 15:55:07

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:45:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:53:56
User entered 'US'	(b) (4) System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Apr 2021 20:03:34
User entered '2'	System	08 Apr 2021 14:45:27
User entered '1'	System	24 Mar 2021 15:57:12

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
User entered '09/Apr/2021 13:03'	(b) (4) System	09 Apr 2021 20:03:34

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:00:15

**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)	26 Apr 2021 19:40:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:34



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'USA-US300-2021-MRNA-1273-P301000023'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16



US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Carlos'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Fierro'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '16300 College Blvd'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Shawnee'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'KS'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '66219'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'US'	System	15 Apr 2021 15:19:42

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:26:59
User entered '1'	System	15 Apr 2021 15:19:42



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'USA-US300-2021-MRNA-1273-P301000023'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16



US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Carlos'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Fierro'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '16300 College Blvd'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Shawnee'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'KS'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '66219'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'US'	System	15 Apr 2021 15:19:42

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:26:59
User entered '1'	System	15 Apr 2021 15:19:42



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
User entered '15/Apr/2021 11:19'	(b) (4) System	15 Apr 2021 15:19:42

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:15

**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)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 15:19:42

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'USA-US300-2021-MRNA-1273-P301000023'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Yes (Y)'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'No (N)'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Carlos'	System	15 Apr 2021 15:16:16

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Fierro'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '16300 College Blvd'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'Shawnee'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'KS'	System	15 Apr 2021 15:16:16

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered '66219'	System	15 Apr 2021 15:16:16



**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:42:34
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'US'	System	15 Apr 2021 15:19:42

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:26:59
User entered '1'	System	15 Apr 2021 15:19:42

**US3312379**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000023**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:00:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:48
User entered '26/Apr/2021 15:26'	(b) (4) System	26 Apr 2021 20:26:59

US3312379

Folder: SAE USA-US300-2021-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:15

**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.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:26:59