

US3012096 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:53:21

All time stamps listed in this document are displayed in GMT

US3012096

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 00:49:10

Generated On: 09 Jun 2021 14:53:21

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[Participant ID](#)

US3012096

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

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US3012096

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	GERD
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 (3)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	DIABETES, TYPE II
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	DEPRESSIOIN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	HERNIATED DISC : L4
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 (11)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	NEUROPATHY (SENSOR), BILATERAL FEET
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 (12)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	BACK SPASMS
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 (14)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:33 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:33
Height ( <i>xxx.x</i> )	62.1 in
Weight ( <i>xxx.x</i> )	203.6 lb
BMI ( <i>xxx.x</i> )	37.19670 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*) 10 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*) UN UNK 1996

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: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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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** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:18:25

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143164

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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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)	10 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:33
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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)	10 AUG 2020
Time of assessment (00:00-23:59)	19:11 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:11
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 18:40 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 18:40

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) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	17:35 (24 HR)
Collection date and time (derived)	10 AUG 2020 17:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:06	10 AUG 2020 18:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:12

PC Open Date & Time

10 AUG 2020 19:00

PC Close Date & Time

10 AUG 2020 21:30

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 22:26

PC Open Date & Time

10 AUG 2020 22:25

PC Close Date & Time

11 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 11:46

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:53

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**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

97.6 °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

15 AUG 2020 08:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**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

97.6 °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

16 AUG 2020 11:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**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

98.1 °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

16 AUG 2020 18:59

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**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

10 AUG 2020 19:13

PC Open Date & Time

10 AUG 2020 19:00

PC Close Date & Time

10 AUG 2020 21:30

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**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

10 AUG 2020 22:27

PC Open Date & Time

10 AUG 2020 22:25

PC Close Date & Time

11 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**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

11 AUG 2020 17:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 11:47

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**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

13 AUG 2020 21:53

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 08:23

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**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

16 AUG 2020 11:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**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

16 AUG 2020 19:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**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 ☐

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:14
PC Open Date & Time	10 AUG 2020 19:00
PC Close Date & Time	10 AUG 2020 21:30

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**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 ☐



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 22:27
PC Open Date & Time	10 AUG 2020 22:25
PC Close Date & Time	11 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 11:47
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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)

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:54
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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)



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 08:24
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**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)

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:00
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3012096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3012096

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:24

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	14:07 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:07
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:03
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3012096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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) 08 SEP 2020

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

Treatment Date and Time (derived) 08 SEP 2020 15:24

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



US3012096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

08 SEP 2020 14:50

US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:19	08 SEP 2020 14:19
Nasopharyngeal Swab 2	No		

US3012096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**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 08 SEP 2020 15:58

PC Open Date & Time 08 SEP 2020 15:44

PC Close Date & Time 08 SEP 2020 18:14

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**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 98.1 °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	09 SEP 2020 07:48
PC Open Date & Time	08 SEP 2020 19:09
PC Close Date & Time	09 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**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 98.1 °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):

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

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

PC Time Stamp 09 SEP 2020 18:49

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 11:29

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

12 SEP 2020 15:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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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

97.8 °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

13 SEP 2020 16:53

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 08:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**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

08 SEP 2020 15:59

PC Open Date & Time

08 SEP 2020 15:44

PC Close Date & Time

08 SEP 2020 18:14

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**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

09 SEP 2020 07:49

PC Open Date & Time

08 SEP 2020 19:09

PC Close Date & Time

09 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**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

09 SEP 2020 18:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**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

11 SEP 2020 11:29

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**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

12 SEP 2020 15:18

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**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

13 SEP 2020 16:53

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**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

15 SEP 2020 08:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**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 ☐

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:59
PC Open Date & Time	08 SEP 2020 15:44
PC Close Date & Time	08 SEP 2020 18:14

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**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 ☐

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 07:50
PC Open Date & Time	08 SEP 2020 19:09
PC Close Date & Time	09 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 ☒



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 11:30
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**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  
EAB) (1725)

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US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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)

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:18
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2195



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:54
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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

113 of 2195

EAB) (1725)

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 08:11
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3012096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3012096

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	6 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:16 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 14:16
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

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.*

US3012096

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

14:53 (24 HR)

Collection date and time (derived)

6 OCT 2020 14:53

US3012096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:18:25

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59



US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 06:24:05

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 04:32:18

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

25 NOV 2020 07:03:47

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

02 DEC 2020 07:48:08

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 13:40:59

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

17 DEC 2020 07:46:14

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

23 DEC 2020 17:15:40

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 07:52:14

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59



US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

13 JAN 2021 05:27:10

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

21 JAN 2021 10:58:23

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

27 JAN 2021 17:04:55

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

05 FEB 2021 12:01:14

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 12:06:03

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 10:20:07

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 21:49:37

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

03 MAR 2021 06:54:59

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59



US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

13 MAR 2021 17:38:18

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

18 MAR 2021 04:09:47

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

24 MAR 2021 17:25:13

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

31 MAR 2021 16:31:26

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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

08 APR 2021 13:48:36

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 14:33:50

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:29:35

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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="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"/>

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 NOV 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐  
Yes ☐

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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"/>



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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"/>

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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"/>



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3012096**

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

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**Generated On: 09 Jun 2021 14:53:21**

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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"/>



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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°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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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"/>



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

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US3012096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

**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 ☐  
Yes ☐

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



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3012096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:53:21

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
Yes	No	02 MAR 2021 11:04:32

US3012096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:24:31

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:24:31

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3012096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3012096

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 14:50:24

Generated On: 09 Jun 2021 14:53:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 14:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

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.*

US3012096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 MAR 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	08 MAR 2021 14:25

US3012096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012096

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 14:50:24

Generated On: 09 Jun 2021 14:53:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3012096

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 14:50:24

Generated On: 09 Jun 2021 14:53:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3012096**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

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*

**US3012096**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3012096**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:53:21**

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

**US3012096**

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

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

**Generated On: 09 Jun 2021 14:53:21**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3012096

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 JAN 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

US3012096

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 20:39:12

Generated On: 09 Jun 2021 14:53:21

Date of updated informed consent (dd MMM yyyy) 22 JAN 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) 22 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 \_\_\_\_\_

US3012096

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

10:12 (24 HR)

Collection date and time (derived)

22 JAN 2021 10:12



US3012096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:04
Collection Date and Time (derived)	22 JAN 2021 10:04

US3012096

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:26:49

Generated On: 09 Jun 2021 14:53:21

AEID	USA-US006-2021-MRNA-1273-P30 1000008
Adverse event	CROHN'S DISEASE
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)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 APR 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)	04 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	07 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:26:49

Generated On: 09 Jun 2021 14:53:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ONGOING SYMPTOMS
Narrative	

US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:26:49

Generated On: 09 Jun 2021 14:53:21

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SITE MADE AWARE OF SAE ON  
05-APR-2021 DURING DAY 239  
SAFETY CALL WHEN  
QUERYING SUBJECT ABOUT  
NEW MEDICATIONS. SUBJECT  
SOUGHT MEDICAL ATTENTION  
FOR ABDOMINAL PAIN ON  
03-NOV-2021. SUBJECT WAS  
ADMITTED TO HOSPITAL ON  
03-NOV-2021 AND DIAGNOSED  
WITH CROHN'S DISEASE,  
DISCHARGED FROM HOSPITAL  
06-NOV-2021. MEDICAL  
RECORDS REQUESTED,  
PENDING RECEIPT FOR  
ADDITIONAL INFORMATION  
AND MEDICATIONS. PER PI,  
SAE NOT RELATED TO IP OR  
STUDY PROCEDURE. CON-MED  
(HUMIRA) STARTED FOR  
MANAGEMENT OF SAE ON  
27-MAR-2021. CURRENTLY  
ONGOING/NOT RESOLVED.

---

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

---

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 14:50:24

Generated On: 09 Jun 2021 14:53:21

---

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

Yes ☒

No ☐

---

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

---

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2012	
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) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication ZIPRASIDONE

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (5)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication ZIPRASIDONE

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DEPRESSION

Dose per administration 160

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) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication TIZANIDINE

Prophylaxis Yes ☐  
No ☒

Indication BACK SPASMS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES, TYPE II

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 (9)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY, BILATERAL FEET

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐  
No ☒

Indication PAIN, BACK AND FEET, DUE TO  
NEUROPATHY

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 2019	
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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)

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 MAY 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 ☐

PRODUCTION RELEASE (v12.003

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US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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)		9 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) 9 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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)		1 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)		1 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"/>

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

Name of Medication ADALIMUMAB

Prophylaxis Yes ☐  
No ☒

Indication CROHN'S DISEASE (AE #1)

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 2 WEEKS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 14:50:23

Generated On: 09 Jun 2021 14:53:21

	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 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)	_____	
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 00:49:11

Generated On: 09 Jun 2021 14:53:21

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3012096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:53:21

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

US3012096

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:53:21

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 ☐

US3012096

Folder: SAE USA-US006-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 15:32:06

Generated On: 09 Jun 2021 14:53:21

SAEID	USA-US006-2021-MRNA-1273-P301000008
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3012096

Folder: SAE USA-US006-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 15:32:06

Generated On: 09 Jun 2021 14:53:21

SAEID	USA-US006-2021-MRNA-1273-P301000008
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 11:36
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

US3012096

Folder: SAE USA-US006-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 15:32:06

Generated On: 09 Jun 2021 14:53:21

SAEID	USA-US006-2021-MRNA-1273-P301000008
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/APR/2021 15:53
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

US3012096 (Prod: Benchmark Research-Austin)

**US3012096**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:53:21**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:13:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'US3012096'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 21:09:23



US3012096

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:55:46

**US3012096**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 21:09:24

**US3012096**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:55:46

**US3012096**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'SCRN'	System	10 Aug 2020 23:55:46

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 21:09:25

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '59'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'YEARS'	System	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '59'	System	10 Aug 2020 23:56:46



**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Female (F)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'I'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03



**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:53:21**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Aug 2020 23:56:03

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Aug 2020'	System	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2020'	System	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Amendment 2 (2)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46



**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:46

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 21:09:24

**US3012096**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:53:21**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'I'	System	10 Aug 2020 23:56:50

**US3012096**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Aug 2020 23:56:50

**US3012096**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:53:21**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:45:02

US3012096

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
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)	11 Aug 2020 00:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:47:17
Data point term sent to Coder	System	11 Aug 2020 00:46:10
User entered 'Seasonal Allergies'	Katherine Davis (b) (4)	11 Aug 2020 00:45:22



**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 1995'	Katherine Davis (b) (4)	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1995'	System	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1995'	System	11 Aug 2020 00:45:22

**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:22



**US3012096**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:22

US3012096

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 00:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:47:17
Data point term sent to Coder	System	11 Aug 2020 00:46:10
User entered 'GERD'	Katherine Davis (b) (4)	11 Aug 2020 00:45:38
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2017'	Katherine Davis (b) (4)	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2017'	System	11 Aug 2020 00:45:38



**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2017'	System	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:38

**US3012096**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:38

US3012096

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:29:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:30:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:30:31
Data point term sent to Coder	System	27 Aug 2020 15:52:31
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:51:53
User entered 'diabetes, type ii' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:51:53
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' answered with 'CM entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:51:38
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 08:35:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 10:53:04

US3012096

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder User entered 'DM2'	Coder Import (b) (4) (b) (4) System Katherine Davis (b) (4) (b) (4)	11 Aug 2020 10:53:04  11 Aug 2020 00:46:10 11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2010'	Katherine Davis (b) (4)	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:45:57



**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2010'	System	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2010'	System	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:57

**US3012096**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:45:57

US3012096

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:48:17
Data point term sent to Coder	System	11 Aug 2020 00:47:11
User entered 'Obesity'	Katherine Davis (b) (4)	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 1995'	Katherine Davis (b) (4)	11 Aug 2020 00:46:15



**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1995'	System	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1995'	System	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:15

**US3012096**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:15



US3012096

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 07:24:01
Query 'Per DM CLR: Please note that there is no Con Jennifer Leyva Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' answered with 'CM entered' (Site from DM).	(b) (4) (b) (4)	27 Aug 2020 15:52:02
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 08:35:14
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:48:17
Data point term sent to Coder	System	11 Aug 2020 00:47:11
User entered 'Hypertension'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:46:33

US3012096

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	11 Aug 2020 17:42:06
User entered 'UN UNK 2012' reason for change: Data Entry Error	System	11 Aug 2020 17:42:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jennifer Leyva (b) (4)	11 Aug 2020 17:42:06
User entered 'u UNK 2012' (non-conformant).	(b) (4)	11 Aug 2020 00:46:33
	System	11 Aug 2020 00:46:33
	Katherine Davis (b) (4)	11 Aug 2020 00:46:33
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2012'	System	11 Aug 2020 17:42:06
User entered empty.	System	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2012'	System	11 Aug 2020 17:42:06
User entered empty.	System	11 Aug 2020 00:46:33



**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:33

**US3012096**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:33

US3012096

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:48:17
Data point term sent to Coder	System	11 Aug 2020 00:47:14
User entered 'hypercholesterolemia'	Katherine Davis (b) (4)	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2018'	Katherine Davis (b) (4)	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:46:55



**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2018'	System	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2018'	System	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:55

**US3012096**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:46:55

US3012096

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:15:58
Query 'Per DM CLR: Please note that there is no Con Jennifer Leyva Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' answered with 'Untreated' (Site from DM).	(b) (4) (b) (4)	27 Aug 2020 15:52:14
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 08:35:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:48:17
Data point term sent to Coder	System	11 Aug 2020 00:47:12
User entered 'COPD'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2019'	Katherine Davis (b) (4)	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:47:12



**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2019'	System	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2019'	System	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:47:12

**US3012096**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:47:12

US3012096

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:49:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 00:49:17
Data point term sent to Coder	System	11 Aug 2020 00:48:15
User entered 'Depressioin'	Katherine Davis (b) (4)	11 Aug 2020 00:47:27
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2008'	Katherine Davis (b) (4)	11 Aug 2020 00:47:27



**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2008'	System	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2008'	System	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:47:27

**US3012096**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:47:27



US3012096

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 07:49:22
Query 'Per DM CLR: Please note that there is no Con Jennifer Leyva Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' answered with 'CM entered' (Site from DM).	(b) (4) (b) (4)	27 Aug 2020 15:52:26
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 08:36:04
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:49:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 00:49:17
Data point term sent to Coder	System	11 Aug 2020 00:48:15
User entered 'Bipolar Disorder'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2008'	Katherine Davis (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2008'	System	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2008'	System	11 Aug 2020 00:48:07



**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:48:07

**US3012096**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:48:07

US3012096

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 11:34:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 11:34:25
Data point term sent to Coder	System	11 Aug 2020 00:49:16
User entered 'Herniated Disc : L4'	Katherine Davis (b) (4)	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2014'	Katherine Davis (b) (4)	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:48:34



**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2014'	System	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2014'	System	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:48:34

**US3012096**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:48:34

US3012096

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please review term NEPHROPATHY : BILATERAL FEET and verify what diagnosis should be more appropriate recording NEPHROPATHY or NEUROPATHY BILATERAL FEET. If NEUROPATHY, please specify the type: motor or sensor. Please update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 08:09:14
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 19:03:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 19:03:41
Data point term sent to Coder	System	27 Aug 2020 15:54:38
Query 'Per DM CLR: Please review term NEPHROPATHY : BILATERAL FEET and verify what diagnosis should be more appropriate recording NEPHROPATHY or NEUROPATHY BILATERAL FEET. If NEUROPATHY, please specify the type: motor or sensor. Please update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:53:43
User entered 'NEUROPATHY (sensor), BILATERAL FEET' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:53:39
Data point term sent to Coder	System	27 Aug 2020 15:53:32
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:53:04
User entered 'NEPHROPATHY, BILATERAL FEET' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:53:04
User opened query 'Per DM CLR: Please review term NEPHROPATHY : BILATERAL FEET and verify what diagnosis should be more appropriate recording NEPHROPATHY or NEUROPATHY BILATERAL FEET. If NEUROPATHY, please specify the type: motor or sensor. Please update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 08:43:04

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:15:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:15:35
Data point term sent to Coder	System	11 Aug 2020 00:50:16
User entered 'Nephropathy : Bilateral Feet'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 2017'	Katherine Davis (b) (4)	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:49:19



**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2017'	System	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2017'	System	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:49:19

**US3012096**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Aug 2020 00:49:19

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:52:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'MEDICAL HISTORY UPDATED' (Site from DM).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:35:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:01:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:31:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:31:43
Data point term sent to Coder	System	27 Aug 2020 15:58:57
User entered 'hysterectomy'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:58:52



**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'UN UNK 1996'	Jennifer Leyva (b) (4)	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Jennifer Leyva (b) (4)	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'UN UNK 1996'	Jennifer Leyva (b) (4)	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Jennifer Leyva (b) (4)	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1996'	System	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1996'	System	27 Aug 2020 15:58:52

**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1996'	System	27 Aug 2020 15:58:52



**US3012096**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1996'	System	27 Aug 2020 15:58:52

US3012096

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 20:34:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 20:34:44
Data point term sent to Coder	System	18 Sep 2020 20:34:00
User entered 'BACK SPASMS'	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'UN UNK 2014'	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Lamar Box (b) (4)	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 2014'	System	18 Sep 2020 20:33:25



**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '2014'	System	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	18 Sep 2020 20:33:25

**US3012096**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	18 Sep 2020 20:33:25

US3012096

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 20:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 20:35:46
Data point term sent to Coder	System	18 Sep 2020 20:35:03
User entered 'UTERINE FIBROIDS'	Lamar Box (b) (4)	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'UN UNK 1996'	Lamar Box (b) (4)	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Lamar Box (b) (4)	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Lamar Box (b) (4)	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'UN UNK 1996'	Lamar Box (b) (4)	18 Sep 2020 20:34:59



**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Lamar Box (b) (4)	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1996'	System	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1996'	System	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1996'	System	18 Sep 2020 20:34:59

**US3012096**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1996'	System	18 Sep 2020 20:34:59

US3012096

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 21:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 21:33:37
Data point term sent to Coder	System	11 Nov 2020 21:32:59
User entered 'Post Menopausal'	Pamela Fidler (b) (4)	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 1996'	(b) (4) Pamela Fidler (b) (4)	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4) Pamela Fidler (b) (4)	11 Nov 2020 21:32:05



**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4)	11 Nov 2020 21:32:05
	Pamela Fidler (b) (4)	
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	(b) (4)	11 Nov 2020 21:32:05
	Pamela Fidler (b) (4)	
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'Jan 1996'	System	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '1996'	System	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Nov 2020 21:32:05

**US3012096**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered empty.	System	11 Nov 2020 21:32:05

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16



US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '16:33'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered '10 Aug 2020 16:33'	System	11 Aug 2020 00:50:16

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
Query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 02:09:42
User opened query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 02:05:35
User entered '62.1' in	Katherine Davis (b) (4)	11 Aug 2020 00:50:16
DataPoint set to visible.	(b) (4) System	10 Aug 2020 23:56:50

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '203.6' lb	Katherine Davis (b) (4)	11 Aug 2020 00:50:16
DataPoint set to visible.	System	10 Aug 2020 23:56:50

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
Amendment Manager: User entered '37.19670'	System	16 Sep 2020 23:50:50
User entered '37.2'	System	11 Aug 2020 00:50:16
DataPoint set to visible.	System	10 Aug 2020 23:56:50

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'kg/m2'	System	11 Aug 2020 00:50:16
DataPoint set to visible.	System	10 Aug 2020 23:56:50

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND for all other vital signs fields. Please review and update per the CCGs.' (Site from DM). Query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND for all other vital signs fields. Please review and update per the CCGs.' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 06:40:13
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:07:24
User opened query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND for all other vital signs fields. Please review and update per the CCGs.' (Site from DM). User entered '98.3' F	Jennifer Leyva (b) (4) (b) (4) (b) (4), (b) (6)	08 Sep 2020 20:07:19
	(b) (4)	01 Sep 2020 02:23:56
	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:50:16



US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:07:19
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:50:16

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:07:19
User entered '82'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'bpm'	System	11 Aug 2020 00:50:16

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered missing code ND - Not Done; reason for change New Information	(b) (4)	08 Sep 2020 20:07:19
User entered '14'	Jennifer Leyva (b) (4)	11 Aug 2020 00:50:16
	(b) (4)	

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'breaths/min'	System	11 Aug 2020 00:50:16

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered missing code ND - Not Done; reason for change New Information	(b) (4)	08 Sep 2020 20:07:19
User entered '131'	Jennifer Leyva (b) (4)	11 Aug 2020 00:50:16
	(b) (4)	

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'mmHg'	System	11 Aug 2020 00:50:16



US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:07:19
User entered '86'	Katherine Davis (b) (4)	11 Aug 2020 00:50:16

**US3012096**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User entered 'mmHg'	System	11 Aug 2020 00:50:16

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50

US3012096

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50

**US3012096**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:53:21**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:50:38

US3012096

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:47:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 20:08:13
User entered '10 Aug 2020'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:50:38

**US3012096**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:53:21**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

US3012096

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:51:35



US3012096

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 08:24:13
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' answered with 'MH item added' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:58:59
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 11:25:27
User entered 'Surgically sterile (SURGICALLY STERILE)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:51:35

US3012096

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

**US3012096**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'un UNK 1996'	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

**US3012096**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:53:21**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

US3012096

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:21

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

**US3012096**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:53:21**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:51:35

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:52:26



US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26



US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

**US3012096**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:53:21**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'I'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26



US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '0'	Katherine Davis (b) (4)	11 Aug 2020 00:52:26

US3012096

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:39:50
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4) Katherine Davis (b) (4)	11 Aug 2020 00:52:26

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:59

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	Katherine Davis (b) (4)	11 Aug 2020 00:52:59

US3012096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4)	11 Aug 2020 00:52:59

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'VISIT1'	System	11 Aug 2020 00:52:59

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:14:15



US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:26:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:26:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:14:15
User entered '143164' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:14:15

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:14:15

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:53:27

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:53:27
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:53:27
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:53:21**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:53:27
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:53:27
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:21

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:03:45
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 14:12:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 14:12:21
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 11:48:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:22:44



US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 06:39:42
Query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:50
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:45
User opened query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 02:06:42
User entered '62.1' in	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jennifer Leyva (b) (4)	08 Sep 2020 20:06:45
change New Information	(b) (4)	
User entered '203.6' lb	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 06:39:42
Query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:50
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:45
User opened query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 02:06:42
User entered '62.1' in	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:06:45
	(b) (4)	
User entered '203.6' lb	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:53:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '16:33'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37



US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '10 Aug 2020 16:33'	(b) (4), (b) (6) System	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '98.3' F	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '82'	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'bpm'	(b) (4), (b) (6) System	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14'	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Aug 2020 00:54:37



US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '131'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '86'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 06:39:42
Query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:50
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:06:45
User opened query 'Per CDM: Screening and Visit 1 Day1 occurred on the same day. Per pages 15-16 of the CCGs, record the Height and Weight at Screening and enter ND at Visit 1 Day 1. Please review and update per the CCGs.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 02:06:42
User entered '62.1' in	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:54:37

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jennifer Leyva (b) (4)	08 Sep 2020 20:06:45
change New Information	(b) (4)	
User entered '203.6' lb	Katherine Davis (b) (4)	11 Aug 2020 00:54:37
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:56:06

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	



US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:56:06

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'post-dose assessment is 30 minutes' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:37:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'post-dose assessment is 30 minutes' (Site from System).	Jennifer Leyva (b) (4)	11 Aug 2020 12:12:34
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '19:11'		11 Aug 2020 00:56:06
	Katherine Davis (b) (4)	
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '10 Aug 2020 19:11'	(b) (4), (b) (6) System	11 Aug 2020 00:56:06

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '98.8' F	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '84'	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'bpm'	(b) (4), (b) (6) System	11 Aug 2020 00:56:06



US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14'	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Aug 2020 00:56:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '136'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:56:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	11 Aug 2020 00:56:06

US3012096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '82'	Katherine Davis (b) (4)	11 Aug 2020 00:56:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	11 Aug 2020 00:56:06

US3012096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:06:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:56:21
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 20:06:26
	(b) (4)	
User entered '10 Aug 2020'	Katherine Davis (b) (4)	11 Aug 2020 00:56:21
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Aug 2020 23:57:20

US3012096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Aug 2020 23:57:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Aug 2020 23:57:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	10 Aug 2020 23:57:20

US3012096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '10 Aug 2020'	Jennifer Leyva (b) (4)	10 Aug 2020 23:57:20
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '18:40'	Jennifer Leyva (b) (4)	10 Aug 2020 23:57:20
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:53:21**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '10 Aug 2020 18:40'	(b) (4), (b) (6) System	10 Aug 2020 23:57:20

US3012096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	Jennifer Leyva (b) (4)	10 Aug 2020 23:57:20
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'ONCE'	(b) (4), (b) (6) System	10 Aug 2020 23:57:20

US3012096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	10 Aug 2020 23:57:20

US3012096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:57:12
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '10 Aug 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:57:12

US3012096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '17:35'	Katherine Davis (b) (4)	11 Aug 2020 00:57:12
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '10 Aug 2020 17:35'	(b) (4), (b) (6) System	11 Aug 2020 00:57:12

US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '10 Aug 2020'	Katherine Davis (b) (4)	11 Aug 2020 00:57:51
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:57:51



US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:57:51
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:53:21**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '18:06'	Katherine Davis (b) (4)	11 Aug 2020 00:57:51
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '10 Aug 2020 18:06'	(b) (4), (b) (6) System	11 Aug 2020 00:57:51

US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	11 Aug 2020 00:57:51

US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	11 Aug 2020 00:57:51
	(b) (4)	

US3012096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	11 Aug 2020 00:57:51
	(b) (4)	

**US3012096**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered empty.	(b) (4), (b) (6) System	11 Aug 2020 00:57:51

US3012096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	11 Aug 2020 00:58:35
	(b) (4)	



**US3012096**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	11 Aug 2020 00:58:35

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:12:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '318395d0-916a-452e-adaa-1b0de2a69875' User entered 'Yes (Y)'	System	11 Aug 2020 00:12:39
	System	11 Aug 2020 00:12:39

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:12:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '318395d0-916a-452e-adaa-1b0de2a69875' User entered '98.8'	System	11 Aug 2020 00:12:39
	System	11 Aug 2020 00:12:39

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:12:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '318395d0-916a-452e-adaa-1b0de2a69875' User entered 'No (N)'	System	11 Aug 2020 00:12:39
	System	11 Aug 2020 00:12:39

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:12:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '318395d0-916a-452e-adaa-1b0de2a69875' User entered '10 Aug 2020 19:12'	System	11 Aug 2020 00:12:39
	System	11 Aug 2020 00:12:39

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 19:00'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 21:30'	System	10 Aug 2020 23:57:20



US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:25:45', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '42312e80-7599-4d2f-8fb7-27634cb6e31c' User entered 'Yes (Y)'	System	11 Aug 2020 03:26:16
	System	11 Aug 2020 03:26:16

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:25:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '42312e80-7599-4d2f-8fb7-27634cb6e31c' User entered '98.2'	System	11 Aug 2020 03:26:16
	System	11 Aug 2020 03:26:16

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '42312e80-7599-4d2f-8fb7-27634cb6e31c'	System	11 Aug 2020 03:26:16
User entered 'No (N)'	System	11 Aug 2020 03:26:16

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '42312e80-7599-4d2f-8fb7-27634cb6e31c' User entered '10 Aug 2020 22:26'	System	11 Aug 2020 03:26:16
	System	11 Aug 2020 03:26:16

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 22:25'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 2'	System	10 Aug 2020 23:57:20



US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:27:31', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3c9bf77c-7267-4aef-86c4-613cd68b3ac4' User entered 'Yes (Y)'	System	11 Aug 2020 22:28:04
	System	11 Aug 2020 22:28:04

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:27:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3c9bf77c-7267-4aef-86c4-613cd68b3ac4' User entered '97.8'	System	11 Aug 2020 22:28:04
	System	11 Aug 2020 22:28:04

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:27:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3c9bf77c-7267-4aef-86c4-613cd68b3ac4'	System	11 Aug 2020 22:28:04
User entered 'No (N)'	System	11 Aug 2020 22:28:04

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:28:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3c9bf77c-7267-4aef-86c4-613cd68b3ac4' User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:28:04
	System	11 Aug 2020 22:28:04

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 3'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'f3d85806-9534-4a2c-86fc-7c0fa21013e4' User entered 'Yes (Y)'	System	13 Aug 2020 16:46:35
	System	13 Aug 2020 16:46:35



US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:18', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'f3d85806-9534-4a2c-86fc-7c0fa21013e4' User entered '96.7'	System	13 Aug 2020 16:46:35
	System	13 Aug 2020 16:46:35

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'f3d85806-9534-4a2c-86fc-7c0fa21013e4'	System	13 Aug 2020 16:46:35
User entered 'No (N)'	System	13 Aug 2020 16:46:35

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'f3d85806-9534-4a2c-86fc-7c0fa21013e4' User entered '13 Aug 2020 11:46'	System	13 Aug 2020 16:46:35
	System	13 Aug 2020 16:46:35

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 4'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:52:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fab00973-5ca3-43c7-8486-0fc21527e277'	System	14 Aug 2020 02:53:20
User entered 'Yes (Y)'	System	14 Aug 2020 02:53:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:52:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fab00973-5ca3-43c7-8486-0fc21527e277'	System	14 Aug 2020 02:53:20
User entered '97.6'	System	14 Aug 2020 02:53:20



US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fab00973-5ca3-43c7-8486-0fc21527e277'	System	14 Aug 2020 02:53:20
User entered 'No (N)'	System	14 Aug 2020 02:53:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fab00973-5ca3-43c7-8486-0fc21527e277'	System	14 Aug 2020 02:53:20
User entered '13 Aug 2020 21:53'	System	14 Aug 2020 02:53:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 5'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9c12018e-3db9-42ce-bdba-13299440601e' User entered 'Yes (Y)'	System	15 Aug 2020 13:22:42
	System	15 Aug 2020 13:22:42

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9c12018e-3db9-42ce-bdba-13299440601e' User entered '97.6'	System	15 Aug 2020 13:22:42
	System	15 Aug 2020 13:22:42

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9c12018e-3db9-42ce-bdba-13299440601e' User entered 'No (N)'	System	15 Aug 2020 13:22:42
	System	15 Aug 2020 13:22:42



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9c12018e-3db9-42ce-bdba-13299440601e' User entered '15 Aug 2020 08:22'	System	15 Aug 2020 13:22:42
	System	15 Aug 2020 13:22:42

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 6'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:10:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '57839632-629e-4584-8ad0-04e515ff4615' User entered 'Yes (Y)'	System	16 Aug 2020 16:11:05
	System	16 Aug 2020 16:11:05

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:10:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '57839632-629e-4584-8ad0-04e515ff4615' User entered '97.6'	System	16 Aug 2020 16:11:05
	System	16 Aug 2020 16:11:05

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:10:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '57839632-629e-4584-8ad0-04e515ff4615' User entered 'No (N)'	System	16 Aug 2020 16:11:05
	System	16 Aug 2020 16:11:05

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:03', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '57839632-629e-4584-8ad0-04e515ff4615' User entered '16 Aug 2020 11:11'	System	16 Aug 2020 16:11:05
	System	16 Aug 2020 16:11:05



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 7'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '10b4e2e2-383a-40fb-af21-76759bc3046c' User entered 'Yes (Y)'	System	16 Aug 2020 23:59:36
	System	16 Aug 2020 23:59:36

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '10b4e2e2-383a-40fb-af21-76759bc3046c' User entered '98.1'	System	16 Aug 2020 23:59:36
	System	16 Aug 2020 23:59:36

US3012096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '10b4e2e2-383a-40fb-af21-76759bc3046c'	System	16 Aug 2020 23:59:36
User entered 'No (N)'	System	16 Aug 2020 23:59:36

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:33', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '10b4e2e2-383a-40fb-af21-76759bc3046c' User entered '16 Aug 2020 18:59'	System	16 Aug 2020 23:59:36
	System	16 Aug 2020 23:59:36

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '558966af-ee68-44c9-837b-5b478428d926'	System	11 Aug 2020 00:13:40
User entered 'None (1)'	System	11 Aug 2020 00:13:40

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '558966af-ee68-44c9-837b-5b478428d926' User entered 'No (N)'	System	11 Aug 2020 00:13:40
	System	11 Aug 2020 00:13:40

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '558966af-ee68-44c9-837b-5b478428d926' User entered 'No (N)'	System	11 Aug 2020 00:13:40
	System	11 Aug 2020 00:13:40

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '558966af-ee68-44c9-837b-5b478428d926'	System	11 Aug 2020 00:13:40
User entered 'None (1)'	System	11 Aug 2020 00:13:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:38', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '558966af-ee68-44c9-837b-5b478428d926' User entered '10 Aug 2020 19:13'	System	11 Aug 2020 00:13:40
	System	11 Aug 2020 00:13:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 19:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 21:30'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '35a03138-4ce8-4714-9b27-4b483b20c869'	System	11 Aug 2020 03:27:06
User entered 'None (1)'	System	11 Aug 2020 03:27:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:38', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '35a03138-4ce8-4714-9b27-4b483b20c869' User entered 'No (N)'	System	11 Aug 2020 03:27:06
	System	11 Aug 2020 03:27:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '35a03138-4ce8-4714-9b27-4b483b20c869' User entered 'No (N)'	System	11 Aug 2020 03:27:06
	System	11 Aug 2020 03:27:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:26:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '35a03138-4ce8-4714-9b27-4b483b20c869'	System	11 Aug 2020 03:27:06
User entered 'None (1)'	System	11 Aug 2020 03:27:06

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:02', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '35a03138-4ce8-4714-9b27-4b483b20c869' User entered '10 Aug 2020 22:27'	System	11 Aug 2020 03:27:06
	System	11 Aug 2020 03:27:06

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 22:25'	System	10 Aug 2020 23:57:20



US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 2'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:28:35', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27e79dfe-6e54-435a-b0f7-5b6fda383399'	System	11 Aug 2020 22:29:47
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 22:29:47

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:28:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27e79dfe-6e54-435a-b0f7-5b6fda383399'	System	11 Aug 2020 22:29:47
User entered 'No (N)'	System	11 Aug 2020 22:29:47

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:29:21', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27e79dfe-6e54-435a-b0f7-5b6fda383399'	System	11 Aug 2020 22:29:47
User entered 'No (N)'	System	11 Aug 2020 22:29:47

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:29:33', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27e79dfe-6e54-435a-b0f7-5b6fda383399'	System	11 Aug 2020 22:29:47
User entered 'None (1)'	System	11 Aug 2020 22:29:47

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:29:46', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27e79dfe-6e54-435a-b0f7-5b6fda383399'	System	11 Aug 2020 22:29:47
User entered '11 Aug 2020 17:29'	System	11 Aug 2020 22:29:47

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 3'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '23210a27-5305-46cb-a1f8-05db78469fa0'	System	13 Aug 2020 16:47:13
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 16:47:13

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '23210a27-5305-46cb-a1f8-05db78469fa0' User entered 'No (N)'	System	13 Aug 2020 16:47:13
	System	13 Aug 2020 16:47:13

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:46:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '23210a27-5305-46cb-a1f8-05db78469fa0' User entered 'No (N)'	System	13 Aug 2020 16:47:13
	System	13 Aug 2020 16:47:13

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '23210a27-5305-46cb-a1f8-05db78469fa0' User entered 'None (1)'	System	13 Aug 2020 16:47:13
	System	13 Aug 2020 16:47:13

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '23210a27-5305-46cb-a1f8-05db78469fa0' User entered '13 Aug 2020 11:47'	System	13 Aug 2020 16:47:13
	System	13 Aug 2020 16:47:13

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 4'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c9bd272-845d-4497-a1b7-64137204467d' User entered 'None (1)'	System	14 Aug 2020 02:53:53
	System	14 Aug 2020 02:53:53

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c9bd272-845d-4497-a1b7-64137204467d' User entered 'No (N)'	System	14 Aug 2020 02:53:53
	System	14 Aug 2020 02:53:53

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:36', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c9bd272-845d-4497-a1b7-64137204467d' User entered 'No (N)'	System	14 Aug 2020 02:53:53
	System	14 Aug 2020 02:53:53

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c9bd272-845d-4497-a1b7-64137204467d' User entered 'None (1)'	System	14 Aug 2020 02:53:53
	System	14 Aug 2020 02:53:53

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:53:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c9bd272-845d-4497-a1b7-64137204467d' User entered '13 Aug 2020 21:53'	System	14 Aug 2020 02:53:53
	System	14 Aug 2020 02:53:53

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 5'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:50', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ffd71740-f56e-4a57-b713-f65f43788ebf' User entered 'None (1)'	System	15 Aug 2020 13:23:26
	System	15 Aug 2020 13:23:26

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:22:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ffd71740-f56e-4a57-b713-f65f43788ebf' User entered 'No (N)'	System	15 Aug 2020 13:23:26
	System	15 Aug 2020 13:23:26

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ffd71740-f56e-4a57-b713-f65f43788ebf' User entered 'No (N)'	System	15 Aug 2020 13:23:26
	System	15 Aug 2020 13:23:26

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ffd71740-f56e-4a57-b713-f65f43788ebf' User entered 'None (1)'	System	15 Aug 2020 13:23:26
	System	15 Aug 2020 13:23:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:23', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ffd71740-f56e-4a57-b713-f65f43788ebf' User entered '15 Aug 2020 08:23'	System	15 Aug 2020 13:23:26
	System	15 Aug 2020 13:23:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 6'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c504f90e-5ce7-4560-a38f-1d8763ee2acd' User entered 'None (1)'	System	16 Aug 2020 16:11:27
	System	16 Aug 2020 16:11:27

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c504f90e-5ce7-4560-a38f-1d8763ee2acd' User entered 'No (N)'	System	16 Aug 2020 16:11:27
	System	16 Aug 2020 16:11:27

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c504f90e-5ce7-4560-a38f-1d8763ee2acd' User entered 'No (N)'	System	16 Aug 2020 16:11:27
	System	16 Aug 2020 16:11:27

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:21', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c504f90e-5ce7-4560-a38f-1d8763ee2acd' User entered 'None (1)'	System	16 Aug 2020 16:11:27
	System	16 Aug 2020 16:11:27

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c504f90e-5ce7-4560-a38f-1d8763ee2acd' User entered '16 Aug 2020 11:11'	System	16 Aug 2020 16:11:27
	System	16 Aug 2020 16:11:27

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 7'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:44', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27f0828f-d68d-4835-bc4d-f48e3e768d8a' User entered 'None (1)'	System	17 Aug 2020 00:00:06
	System	17 Aug 2020 00:00:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:48', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27f0828f-d68d-4835-bc4d-f48e3e768d8a' User entered 'No (N)'	System	17 Aug 2020 00:00:06
	System	17 Aug 2020 00:00:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:52', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27f0828f-d68d-4835-bc4d-f48e3e768d8a' User entered 'No (N)'	System	17 Aug 2020 00:00:06
	System	17 Aug 2020 00:00:06

US3012096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T18:59:58', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27f0828f-d68d-4835-bc4d-f48e3e768d8a' User entered 'None (1)'	System	17 Aug 2020 00:00:06
	System	17 Aug 2020 00:00:06

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:02', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '27f0828f-d68d-4835-bc4d-f48e3e768d8a' User entered '16 Aug 2020 19:00'	System	17 Aug 2020 00:00:06
	System	17 Aug 2020 00:00:06

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:48', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:53', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:13:57', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:14:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:14:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:14:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e' User entered 'None (0)'	System	11 Aug 2020 00:14:28
	System	11 Aug 2020 00:14:28



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:14:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e'	System	11 Aug 2020 00:14:28
User entered 'No (N)'	System	11 Aug 2020 00:14:28

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T19:14:27', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17144747-938d-445b-824b-157146e38a0e'	System	11 Aug 2020 00:14:28
User entered '10 Aug 2020 19:14'	System	11 Aug 2020 00:14:28

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 19:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 21:30'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:10', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:16', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:20', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:33', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'None (0)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered 'No (N)'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-10T22:27:48', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd0dee2da-8223-451a-9dc6-fcaa34a72f71' User entered '10 Aug 2020 22:27'	System	11 Aug 2020 03:27:50
	System	11 Aug 2020 03:27:50

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Aug 2020 22:25'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 2'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:29:57', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:04', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:16', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'None (0)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:30:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered 'No (N)'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-11T17:31:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '17525b8e-737e-4a54-b93b-f5dce518ca17' User entered '11 Aug 2020 17:31'	System	11 Aug 2020 22:31:07
	System	11 Aug 2020 22:31:07



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 3'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377'	System	13 Aug 2020 16:47:57
User entered 'None (0)'	System	13 Aug 2020 16:47:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377' User entered 'None (0)'	System	13 Aug 2020 16:47:57
	System	13 Aug 2020 16:47:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:27', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377' User entered 'None (0)'	System	13 Aug 2020 16:47:57
	System	13 Aug 2020 16:47:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:31', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377' User entered 'None (0)'	System	13 Aug 2020 16:47:57
	System	13 Aug 2020 16:47:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:36', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377' User entered 'None (0)'	System	13 Aug 2020 16:47:57
	System	13 Aug 2020 16:47:57



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377' User entered 'None (0)'	System	13 Aug 2020 16:47:57
	System	13 Aug 2020 16:47:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377'	System	13 Aug 2020 16:47:57
User entered 'No (N)'	System	13 Aug 2020 16:47:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T11:47:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ab2bf7ad-31e5-491e-be08-b8c36754d377'	System	13 Aug 2020 16:47:57
User entered '13 Aug 2020 11:47'	System	13 Aug 2020 16:47:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 4'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:03', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'None (0)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3' User entered 'No (N)'	System	14 Aug 2020 02:54:41
	System	14 Aug 2020 02:54:41

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-13T21:54:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3ad5f61f-3567-4f3b-a863-9ffe6bcc40f3'	System	14 Aug 2020 02:54:41
User entered '13 Aug 2020 21:54'	System	14 Aug 2020 02:54:41

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 23:57:20



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 5'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:23:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:24:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:24:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:24:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'None (0)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:24:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered 'No (N)'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-15T08:24:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'fedffb61-47be-4de1-adde-884635f5dba9' User entered '15 Aug 2020 08:24'	System	15 Aug 2020 13:24:26
	System	15 Aug 2020 13:24:26

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 6'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:31', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:37', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:46', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'None (0)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:50', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered 'No (N)'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T11:11:53', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '81e85ca5-a660-4b6a-ab99-0a8a007bc7b6' User entered '16 Aug 2020 11:11'	System	16 Aug 2020 16:11:57
	System	16 Aug 2020 16:11:57

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 7'	System	10 Aug 2020 23:57:20

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40



US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:18', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'None (0)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

US3012096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered 'No (N)'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-08-16T19:00:38', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3bcf77dd-3806-478a-a9e1-6860463f36c7' User entered '16 Aug 2020 19:00'	System	17 Aug 2020 00:00:40
	System	17 Aug 2020 00:00:40

**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 23:57:20



**US3012096**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 23:57:20

**US3012096**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	20 Aug 2020 18:10:38
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '20 Aug 2020'	Tambra Dora (b) (4)	20 Aug 2020 18:10:38
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	20 Aug 2020 18:10:38
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Tambra Dora (b) (4)	20 Aug 2020 18:10:38
	(b) (4)	

US3012096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	20 Aug 2020 18:10:42
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 18:10:42

**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	26 Aug 2020 17:28:54
	(b) (4)	



**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '25 Aug 2020'	Michelle Listz (b) (4)	26 Aug 2020 17:28:54
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4)	26 Aug 2020 17:28:54
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Michelle Listz (b) (4)	26 Aug 2020 17:28:54
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	26 Aug 2020 17:29:16
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	26 Aug 2020 17:29:16

**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	01 Sep 2020 15:55:09
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '31 Aug 2020'	Michelle Listz (b) (4)	01 Sep 2020 15:55:09
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4)	01 Sep 2020 15:55:09
	(b) (4)	



**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Michelle Listz (b) (4)	01 Sep 2020 15:55:09
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	01 Sep 2020 15:55:14
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	01 Sep 2020 15:55:14

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:08:13

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	08 Sep 2020 20:08:13
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:08:13
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'VISIT2'	(b) (4), (b) (6) System	08 Sep 2020 20:08:13

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	



US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '08 Sep 2020'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14:07'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '08 Sep 2020 14:07'	(b) (4), (b) (6) System	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '98.1' F	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '76'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	



US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'bpm'	(b) (4), (b) (6) System	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '133'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '77'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:37
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 20:12:37

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	08 Sep 2020 22:26:57



US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '8 Sep 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '16:03'	(b) (4) Katherine Davis (b) (4) (b) (4)	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '8 Sep 2020 16:03'	(b) (4), (b) (6) System	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '98.5' F	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '69'	(b) (4) Katherine Davis (b) (4) (b) (4)	08 Sep 2020 22:26:57



US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'bpm'	(b) (4), (b) (6) System	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14'	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '155'	(b) (4)	
	Katherine Davis (b) (4)	08 Sep 2020 22:26:57
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '80'	(b) (4) Katherine Davis (b) (4) (b) (4)	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 22:26:57

US3012096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:45
	(b) (4)	



**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:53:21**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	08 Sep 2020 20:12:45
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:53:21**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	08 Sep 2020 20:55:27

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '15:24'	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:53:21**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '08 Sep 2020 15:24'	(b) (4), (b) (6) System	08 Sep 2020 20:55:27



US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:55:27
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'ONCE'	(b) (4), (b) (6) System	08 Sep 2020 20:55:27

US3012096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	08 Sep 2020 20:55:27

US3012096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:00
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:00
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14:50'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:00
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '08 Sep 2020 14:50'	(b) (4), (b) (6) System	08 Sep 2020 20:13:00

US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	



US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14:19'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '08 Sep 2020 14:19'	(b) (4), (b) (6) System	08 Sep 2020 20:13:12

US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 20:13:12

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	

US3012096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:12
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 20:13:12



US3012096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:15
	(b) (4)	

**US3012096**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 20:13:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9fde0276-ecc3-48d8-9a73-230c5aabf547'	System	08 Sep 2020 20:58:34
User entered 'Yes (Y)'	System	08 Sep 2020 20:58:34

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:20', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9fde0276-ecc3-48d8-9a73-230c5aabf547' User entered '98.5'	System	08 Sep 2020 20:58:34
	System	08 Sep 2020 20:58:34

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9fde0276-ecc3-48d8-9a73-230c5aabf547'	System	08 Sep 2020 20:58:34
User entered 'No (N)'	System	08 Sep 2020 20:58:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '9fde0276-ecc3-48d8-9a73-230c5aabf547' User entered '08 Sep 2020 15:58'	System	08 Sep 2020 20:58:34
	System	08 Sep 2020 20:58:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 18:14'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:48:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a9a9e982-f4b4-4d19-aefb-419148262a85' User entered 'Yes (Y)'	System	09 Sep 2020 12:48:58
	System	09 Sep 2020 12:48:58

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:48:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a9a9e982-f4b4-4d19-aefb-419148262a85' User entered '98.1'	System	09 Sep 2020 12:48:58
	System	09 Sep 2020 12:48:58

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:48:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a9a9e982-f4b4-4d19-aefb-419148262a85' User entered 'No (N)'	System	09 Sep 2020 12:48:58
	System	09 Sep 2020 12:48:58

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:48:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a9a9e982-f4b4-4d19-aefb-419148262a85' User entered '09 Sep 2020 07:48'	System	09 Sep 2020 12:48:58
	System	09 Sep 2020 12:48:58

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 19:09'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 2'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:48:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa' User entered 'Yes (Y)'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:49:15', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa' User entered '98.1'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:49:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa' User entered 'Yes (Y)'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
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 'MEDICATION ADDED' (Site from System).		21 Sep 2020 10:31:37
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.'	Lamar Box (b) (4)	18 Sep 2020 20:15:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:49:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa'	(b) (4)	
User entered '1'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:53:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:49:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa' User entered '0'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:49:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '83e303fe-7a68-4041-bf93-01ca62c00efa' User entered '09 Sep 2020 18:49'	System	09 Sep 2020 23:49:51
	System	09 Sep 2020 23:49:51

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 3'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd7c1f412-d62e-4278-8c9b-89c7c92ac76e' User entered 'Yes (Y)'	System	11 Sep 2020 16:29:34
	System	11 Sep 2020 16:29:34

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:15', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd7c1f412-d62e-4278-8c9b-89c7c92ac76e' User entered '97.8'	System	11 Sep 2020 16:29:34
	System	11 Sep 2020 16:29:34

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:23', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd7c1f412-d62e-4278-8c9b-89c7c92ac76e' User entered 'No (N)'	System	11 Sep 2020 16:29:34
	System	11 Sep 2020 16:29:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:31', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd7c1f412-d62e-4278-8c9b-89c7c92ac76e' User entered '11 Sep 2020 11:29'	System	11 Sep 2020 16:29:34
	System	11 Sep 2020 16:29:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 4'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:53:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 5'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:03', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8d4732c8-2c50-4778-807c-1d5d3042cdf9' User entered 'Yes (Y)'	System	12 Sep 2020 20:17:29
	System	12 Sep 2020 20:17:29

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:18', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8d4732c8-2c50-4778-807c-1d5d3042cdf9' User entered '98.1'	System	12 Sep 2020 20:17:29
	System	12 Sep 2020 20:17:29

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8d4732c8-2c50-4778-807c-1d5d3042cdf9' User entered 'No (N)'	System	12 Sep 2020 20:17:29
	System	12 Sep 2020 20:17:29

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:28', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8d4732c8-2c50-4778-807c-1d5d3042cdf9' User entered '12 Sep 2020 15:17'	System	12 Sep 2020 20:17:29
	System	12 Sep 2020 20:17:29

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 6'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:15', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8e873315-6b51-4734-aaa7-bdceaf54e0c7' User entered 'Yes (Y)'	System	13 Sep 2020 21:53:38
	System	13 Sep 2020 21:53:38

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8e873315-6b51-4734-aaa7-bdceaf54e0c7' User entered '97.8'	System	13 Sep 2020 21:53:38
	System	13 Sep 2020 21:53:38

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8e873315-6b51-4734-aaa7-bdceaf54e0c7' User entered 'No (N)'	System	13 Sep 2020 21:53:38
	System	13 Sep 2020 21:53:38

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:35', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8e873315-6b51-4734-aaa7-bdceaf54e0c7' User entered '13 Sep 2020 16:53'	System	13 Sep 2020 21:53:38
	System	13 Sep 2020 21:53:38

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 7'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '979b9343-45ce-4514-93dc-fa48b3e562da' User entered 'Yes (Y)'	System	15 Sep 2020 13:10:21
	System	15 Sep 2020 13:10:21

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '979b9343-45ce-4514-93dc-fa48b3e562da' User entered '97.8'	System	15 Sep 2020 13:10:21
	System	15 Sep 2020 13:10:21

US3012096

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '979b9343-45ce-4514-93dc-fa48b3e562da' User entered 'No (N)'	System	15 Sep 2020 13:10:21
	System	15 Sep 2020 13:10:21

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '979b9343-45ce-4514-93dc-fa48b3e562da' User entered '15 Sep 2020 08:10'	System	15 Sep 2020 13:10:21
	System	15 Sep 2020 13:10:21

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e4828cdb-cb9b-4e14-8af3-210f82074802' User entered 'None (1)'	System	08 Sep 2020 20:59:04
	System	08 Sep 2020 20:59:04



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:48', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e4828cdb-cb9b-4e14-8af3-210f82074802' User entered 'No (N)'	System	08 Sep 2020 20:59:04
	System	08 Sep 2020 20:59:04

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:53', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e4828cdb-cb9b-4e14-8af3-210f82074802' User entered 'No (N)'	System	08 Sep 2020 20:59:04
	System	08 Sep 2020 20:59:04

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:58:58', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e4828cdb-cb9b-4e14-8af3-210f82074802' User entered 'None (1)'	System	08 Sep 2020 20:59:04
	System	08 Sep 2020 20:59:04

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e4828cdb-cb9b-4e14-8af3-210f82074802' User entered '08 Sep 2020 15:59'	System	08 Sep 2020 20:59:04
	System	08 Sep 2020 20:59:04

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 18:14'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd87dfeda-c3bc-42f8-99f2-9d32c15c324d'	System	09 Sep 2020 12:49:45
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 12:49:45



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd87dfeda-c3bc-42f8-99f2-9d32c15c324d' User entered 'No (N)'	System	09 Sep 2020 12:49:45
	System	09 Sep 2020 12:49:45

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd87dfeda-c3bc-42f8-99f2-9d32c15c324d' User entered 'No (N)'	System	09 Sep 2020 12:49:45
	System	09 Sep 2020 12:49:45

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:38', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd87dfeda-c3bc-42f8-99f2-9d32c15c324d' User entered 'None (1)'	System	09 Sep 2020 12:49:45
	System	09 Sep 2020 12:49:45

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd87dfeda-c3bc-42f8-99f2-9d32c15c324d' User entered '09 Sep 2020 07:49'	System	09 Sep 2020 12:49:45
	System	09 Sep 2020 12:49:45

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 19:09'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 2'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c866066e-f0bc-4dbd-9b3f-fb4fa6416af9'	System	09 Sep 2020 23:50:24
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 23:50:24



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c866066e-f0bc-4dbd-9b3f-fb4fa6416af9' User entered 'No (N)'	System	09 Sep 2020 23:50:24
	System	09 Sep 2020 23:50:24

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c866066e-f0bc-4dbd-9b3f-fb4fa6416af9' User entered 'No (N)'	System	09 Sep 2020 23:50:24
	System	09 Sep 2020 23:50:24

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c866066e-f0bc-4dbd-9b3f-fb4fa6416af9' User entered 'None (1)'	System	09 Sep 2020 23:50:24
	System	09 Sep 2020 23:50:24

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c866066e-f0bc-4dbd-9b3f-fb4fa6416af9' User entered '09 Sep 2020 18:50'	System	09 Sep 2020 23:50:24
	System	09 Sep 2020 23:50:24

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 3'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4ff60999-65d8-427c-a4b6-23865f8a9770'	System	11 Sep 2020 16:30:06
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 16:30:06



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4ff60999-65d8-427c-a4b6-23865f8a9770' User entered 'No (N)'	System	11 Sep 2020 16:30:06
	System	11 Sep 2020 16:30:06

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4ff60999-65d8-427c-a4b6-23865f8a9770' User entered 'No (N)'	System	11 Sep 2020 16:30:06
	System	11 Sep 2020 16:30:06

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4ff60999-65d8-427c-a4b6-23865f8a9770' User entered 'None (1)'	System	11 Sep 2020 16:30:06
	System	11 Sep 2020 16:30:06

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:29:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4ff60999-65d8-427c-a4b6-23865f8a9770' User entered '11 Sep 2020 11:29'	System	11 Sep 2020 16:30:06
	System	11 Sep 2020 16:30:06

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:53:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 4'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:53:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 5'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:42', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1dfae8b4-e6e3-49cb-b415-eb7271360c2e' User entered 'None (1)'	System	12 Sep 2020 20:18:03
	System	12 Sep 2020 20:18:03

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:48', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1dfae8b4-e6e3-49cb-b415-eb7271360c2e' User entered 'No (N)'	System	12 Sep 2020 20:18:03
	System	12 Sep 2020 20:18:03

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:53', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1dfae8b4-e6e3-49cb-b415-eb7271360c2e' User entered 'No (N)'	System	12 Sep 2020 20:18:03
	System	12 Sep 2020 20:18:03

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:17:57', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1dfae8b4-e6e3-49cb-b415-eb7271360c2e' User entered 'None (1)'	System	12 Sep 2020 20:18:03
	System	12 Sep 2020 20:18:03

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1dfae8b4-e6e3-49cb-b415-eb7271360c2e' User entered '12 Sep 2020 15:18'	System	12 Sep 2020 20:18:03
	System	12 Sep 2020 20:18:03

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 6'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:42', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ff3cc946-e871-4efa-9fe1-6f0647004b24'	System	13 Sep 2020 21:54:01
User entered 'None (1)'	System	13 Sep 2020 21:54:01

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ff3cc946-e871-4efa-9fe1-6f0647004b24' User entered 'No (N)'	System	13 Sep 2020 21:54:01
	System	13 Sep 2020 21:54:01

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:51', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ff3cc946-e871-4efa-9fe1-6f0647004b24' User entered 'No (N)'	System	13 Sep 2020 21:54:01
	System	13 Sep 2020 21:54:01

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:56', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ff3cc946-e871-4efa-9fe1-6f0647004b24'	System	13 Sep 2020 21:54:01
User entered 'None (1)'	System	13 Sep 2020 21:54:01

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:53:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ff3cc946-e871-4efa-9fe1-6f0647004b24' User entered '13 Sep 2020 16:53'	System	13 Sep 2020 21:54:01
	System	13 Sep 2020 21:54:01

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 7'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:25', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '426c931b-0939-4896-8c0c-5d2b81686fd7'	System	15 Sep 2020 13:10:50
User entered 'None (1)'	System	15 Sep 2020 13:10:50

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:35', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '426c931b-0939-4896-8c0c-5d2b81686fd7' User entered 'No (N)'	System	15 Sep 2020 13:10:50
	System	15 Sep 2020 13:10:50

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:39', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '426c931b-0939-4896-8c0c-5d2b81686fd7' User entered 'No (N)'	System	15 Sep 2020 13:10:50
	System	15 Sep 2020 13:10:50

US3012096

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '426c931b-0939-4896-8c0c-5d2b81686fd7'	System	15 Sep 2020 13:10:50
User entered 'None (1)'	System	15 Sep 2020 13:10:50

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:46', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '426c931b-0939-4896-8c0c-5d2b81686fd7'	System	15 Sep 2020 13:10:50
User entered '15 Sep 2020 08:10'	System	15 Sep 2020 13:10:50

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:15', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:22', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'None (0)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered 'No (N)'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-08T15:59:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '022b719a-52f1-4163-badb-41f26cfb58cf' User entered '08 Sep 2020 15:59'	System	08 Sep 2020 20:59:38
	System	08 Sep 2020 20:59:38

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:53:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 18:14'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:49:57', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:01', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:07', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:19', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:23', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'None (0)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered 'No (N)'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T07:50:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'da766f83-ff75-40df-8e14-a517d94ecebb' User entered '09 Sep 2020 07:50'	System	09 Sep 2020 12:50:37
	System	09 Sep 2020 12:50:37

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '08 Sep 2020 19:09'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 2'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:50:49', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:21', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'None (0)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:28', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered 'No (N)'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-09T18:51:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0d0b12f8-f52d-449e-9068-55fe871cebb4' User entered '09 Sep 2020 18:51'	System	09 Sep 2020 23:51:35
	System	09 Sep 2020 23:51:35

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 3'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:20', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'None (0)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered 'No (N)'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-11T11:30:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '1fe732e4-a3b5-42d2-b712-9345f24bfedb' User entered '11 Sep 2020 11:30'	System	11 Sep 2020 16:30:36
	System	11 Sep 2020 16:30:36

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 4'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 5'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:21', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:30', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:34', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'None (0)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered 'No (N)'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-12T15:18:43', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c17ef086-8b5b-474e-b4fc-b2b3299c7153' User entered '12 Sep 2020 15:18'	System	12 Sep 2020 20:18:45
	System	12 Sep 2020 20:18:45



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 6'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:16', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:20', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34



**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:24', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'None (0)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:29', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered 'No (N)'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-13T16:54:32', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a620a49c-a7e4-4882-94a4-6595632224b6' User entered '13 Sep 2020 16:54'	System	13 Sep 2020 21:54:34
	System	13 Sep 2020 21:54:34

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	08 Sep 2020 20:55:27
User entered 'Day 7'	System	08 Sep 2020 20:55:27

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:10:58', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26



US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:02', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:09', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:13', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'None (0)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

US3012096

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:53:21

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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:17', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered 'No (N)'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-09-15T08:11:20', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'ca24e07b-c4b4-45c4-95e3-217281fef5d8' User entered '15 Sep 2020 08:11'	System	15 Sep 2020 13:11:26
	System	15 Sep 2020 13:11:26

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:55:27

**US3012096**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:53:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:55:27



**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 23:08:08

**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 23:08:08

**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 23:08:08

**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 23:08:08

**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 23:08:14

**US3012096**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	17 Sep 2020 23:08:14

**US3012096**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4) (b) (4)	24 Sep 2020 22:58:09

**US3012096**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '24 Sep 2020'	Katherine Davis (b) (4)	24 Sep 2020 22:58:09
	(b) (4)	



**US3012096**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	24 Sep 2020 22:58:09
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	24 Sep 2020 22:58:09
	(b) (4)	

US3012096

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	24 Sep 2020 22:58:16
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 22:58:16

**US3012096**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	30 Sep 2020 00:19:14
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '29 Sep 2020'	Michelle Listz (b) (4)	30 Sep 2020 00:19:14
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4)	30 Sep 2020 00:19:14
	(b) (4)	

US3012096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Michelle Listz (b) (4)	30 Sep 2020 00:19:14
	(b) (4)	



US3012096

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	30 Sep 2020 00:19:17
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	30 Sep 2020 00:19:17

US3012096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 21:37:08
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 21:36:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 21:36:56
User entered 'No (N)'	Lamar Box (b) (4)	07 Oct 2020 01:39:32
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 21:37:08
	(b) (4)	
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	07 Oct 2020 01:39:32
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 21:37:08
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 21:37:08
	(b) (4)	
	(b) (4)	
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 21:36:56
User entered empty.	Lamar Box (b) (4)	07 Oct 2020 01:39:32
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'VISIT3'	(b) (4), (b) (6) System	07 Oct 2020 01:39:32

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '6 Oct 2020'	(b) (4) Lamar Box (b) (4) (b) (4)	07 Oct 2020 01:40:14



US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14:16'	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '6 Oct 2020 14:16'	(b) (4), (b) (6) System	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '98.4' F	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '83'	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'bpm'	(b) (4), (b) (6) System	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14'	Lamar Box (b) (4)	07 Oct 2020 01:40:14
	(b) (4)	



US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '144'	(b) (4) Lamar Box (b) (4) (b) (4)	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:18:26
User entered '84'	(b) (4) Lamar Box (b) (4) (b) (4)	07 Oct 2020 01:40:14

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 01:40:14

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 17:04:06

US3012096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 17:04:06

US3012096

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'No (N)'	Lamar Box (b) (4)	07 Oct 2020 01:40:18
	(b) (4)	



US3012096

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	07 Oct 2020 01:40:18
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	07 Oct 2020 01:40:29
	(b) (4)	

US3012096

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '6 Oct 2020'	Lamar Box (b) (4)	07 Oct 2020 01:40:29
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered '14:53'	Lamar Box (b) (4)	07 Oct 2020 01:40:29
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered '6 Oct 2020 14:53'	(b) (4), (b) (6) System	07 Oct 2020 01:40:29

US3012096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:18:26
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	07 Oct 2020 01:40:32
	(b) (4)	

**US3012096**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	07 Oct 2020 01:40:32

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 64'	System	10 Aug 2020 23:57:20



US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 71'	System	10 Aug 2020 23:57:20

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

[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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-21T06:23:45', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '825e8ce1-2746-4850-a23f-e1bfaa09aacc' User entered 'No (N)'	System	21 Oct 2020 11:24:09
	System	21 Oct 2020 11:24:09

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

Have you been exposed to someone with 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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-21T06:23:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '825e8ce1-2746-4850-a23f-e1bfaa09aacc'	System	21 Oct 2020 11:24:09
User entered 'No (N)'	System	21 Oct 2020 11:24:09

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-21T06:24:05', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '825e8ce1-2746-4850-a23f-e1bf09aacc' User entered '21 Oct 2020 06:24:05'	System	21 Oct 2020 11:24:09
	System	21 Oct 2020 11:24:09

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 23:57:20



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 78'	System	10 Aug 2020 23:57:20

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

[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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-24T04:31:58', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'dc6499c8-4a93-4d4a-aa85-200022c5734a' User entered 'No (N)'	System	24 Oct 2020 09:32:19
	System	24 Oct 2020 09:32:19

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

Have you been exposed to someone with 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 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-24T04:32:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'dc6499c8-4a93-4d4a-aa85-200022c5734a' User entered 'No (N)'	System	24 Oct 2020 09:32:19
	System	24 Oct 2020 09:32:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7022A921-B439-4DBF-8D53-1C9AD26A0FC4)', Time: '2020-10-24T04:32:18', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'dc6499c8-4a93-4d4a-aa85-200022c5734a' User entered '24 Oct 2020 04:32:18'	System	24 Oct 2020 09:32:19
	System	24 Oct 2020 09:32:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:15
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 92'	System	10 Aug 2020 23:57:20



US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered 'Day 99'	System	10 Aug 2020 23:57:20

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

US3012096

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28

**US3012096**

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

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**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:17:28
Data entry locked.	System	10 Aug 2020 23:57:20
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 23:57:20

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-11-25T07:03:26', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '264c14d8-6636-4c3f-bd3e-8f446e7b1313'	System	25 Nov 2020 13:03:51
User entered 'No (N)'	System	25 Nov 2020 13:03:51

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-11-25T07:03:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '264c14d8-6636-4c3f-bd3e-8f446e7b1313'	System	25 Nov 2020 13:03:51
User entered 'No (N)'	System	25 Nov 2020 13:03:51

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-11-25T07:03:47', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '264c14d8-6636-4c3f-bd3e-8f446e7b1313' User entered '25 Nov 2020 07:03:47'	System	25 Nov 2020 13:03:51
	System	25 Nov 2020 13:03:51

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-02T07:47:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8ae5b5b0-9214-4585-826d-ddbfd44d08d2'	System	02 Dec 2020 13:48:10
User entered 'No (N)'	System	02 Dec 2020 13:48:10

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-02T07:48:04', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8ae5b5b0-9214-4585-826d-ddbfd44d08d2'	System	02 Dec 2020 13:48:10
User entered 'No (N)'	System	02 Dec 2020 13:48:10

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-02T07:48:08', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '8ae5b5b0-9214-4585-826d-ddbfd44d08d2'	System	02 Dec 2020 13:48:10
User entered '02 Dec 2020 07:48:08'	System	02 Dec 2020 13:48:10

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-11T13:40:45', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '77a5f3d0-8bc6-4a64-a275-0f393519753a' User entered 'No (N)'	System	11 Dec 2020 19:41:00
	System	11 Dec 2020 19:41:00



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-11T13:40:54', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '77a5f3d0-8bc6-4a64-a275-0f393519753a' User entered 'No (N)'	System	11 Dec 2020 19:41:00
	System	11 Dec 2020 19:41:00

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-11T13:40:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '77a5f3d0-8bc6-4a64-a275-0f393519753a' User entered '11 Dec 2020 13:40:59'	System	11 Dec 2020 19:41:00
	System	11 Dec 2020 19:41:00

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-17T07:46:04', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0f6d2063-c402-411b-a905-334c740f6c39'	System	17 Dec 2020 13:46:19
User entered 'No (N)'	System	17 Dec 2020 13:46:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-17T07:46:10', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0f6d2063-c402-411b-a905-334c740f6c39'	System	17 Dec 2020 13:46:19
User entered 'No (N)'	System	17 Dec 2020 13:46:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-17T07:46:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0f6d2063-c402-411b-a905-334c740f6c39'	System	17 Dec 2020 13:46:19
User entered '17 Dec 2020 07:46:14'	System	17 Dec 2020 13:46:19



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-23T17:15:28', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0e2d1d3f-e8b2-4263-ad6c-4f7bfcd8f098'	System	23 Dec 2020 23:15:44
User entered 'No (N)'	System	23 Dec 2020 23:15:44

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-23T17:15:36', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0e2d1d3f-e8b2-4263-ad6c-4f7bfcd8f098'	System	23 Dec 2020 23:15:44
User entered 'No (N)'	System	23 Dec 2020 23:15:44

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-23T17:15:40', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '0e2d1d3f-e8b2-4263-ad6c-4f7bfcd8f098' User entered '23 Dec 2020 17:15:40'	System	23 Dec 2020 23:15:44
	System	23 Dec 2020 23:15:44

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-31T07:52:07', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e0e201f1-c077-4a78-ad28-5e896c7e1864' User entered 'No (N)'	System	31 Dec 2020 13:52:19
	System	31 Dec 2020 13:52:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-31T07:52:10', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e0e201f1-c077-4a78-ad28-5e896c7e1864' User entered 'No (N)'	System	31 Dec 2020 13:52:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2020-12-31T07:52:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e0e201f1-c077-4a78-ad28-5e896c7e1864' User entered '31 Dec 2020 07:52:14'	System	31 Dec 2020 13:52:19
	System	31 Dec 2020 13:52:19

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-13T05:26:56', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '155b431b-29d4-4dde-833d-474a2c1efa85'	System	13 Jan 2021 11:27:12
User entered 'No (N)'	System	13 Jan 2021 11:27:12

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-13T05:27:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '155b431b-29d4-4dde-833d-474a2c1efa85'	System	13 Jan 2021 11:27:12
User entered 'No (N)'	System	13 Jan 2021 11:27:12

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-13T05:27:10', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '155b431b-29d4-4dde-833d-474a2c1efa85'	System	13 Jan 2021 11:27:12
User entered '13 Jan 2021 05:27:10'	System	13 Jan 2021 11:27:12

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-21T10:58:06', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '11fde0cf-af5a-406e-b613-0652d2b89a65'	System	21 Jan 2021 16:58:26
User entered 'No (N)'	System	21 Jan 2021 16:58:26

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-21T10:58:12', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '11fde0cf-af5a-406e-b613-0652d2b89a65'	System	21 Jan 2021 16:58:26
User entered 'No (N)'	System	21 Jan 2021 16:58:26

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-21T10:58:23', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '11fde0cf-af5a-406e-b613-0652d2b89a65' User entered '21 Jan 2021 10:58:23'	System	21 Jan 2021 16:58:26
	System	21 Jan 2021 16:58:26

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-27T17:04:46', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd9a5e845-149e-46ad-8a0b-0b84696f17dc' User entered 'No (N)'	System	27 Jan 2021 23:06:24
	System	27 Jan 2021 23:06:24

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-27T17:04:51', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd9a5e845-149e-46ad-8a0b-0b84696f17dc' User entered 'No (N)'	System	27 Jan 2021 23:06:24
	System	27 Jan 2021 23:06:24



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-01-27T17:04:55', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd9a5e845-149e-46ad-8a0b-0b84696f17dc' User entered '27 Jan 2021 17:04:55'	System	27 Jan 2021 23:06:24
	System	27 Jan 2021 23:06:24

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-05T12:01:07', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3620fec6-029c-4ead-a3d4-31b4c347fa13'	System	05 Feb 2021 18:02:24
User entered 'No (N)'	System	05 Feb 2021 18:02:24

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-05T12:01:11', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3620fec6-029c-4ead-a3d4-31b4c347fa13'	System	05 Feb 2021 18:02:24
User entered 'No (N)'	System	05 Feb 2021 18:02:24

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-05T12:01:14', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '3620fec6-029c-4ead-a3d4-31b4c347fa13'	System	05 Feb 2021 18:02:24
User entered '05 Feb 2021 12:01:14'	System	05 Feb 2021 18:02:24

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-12T12:05:56', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '00ef3c93-ccc8-456a-a1ec-cbf86ff6c80e' User entered 'No (N)'	System	12 Feb 2021 18:08:43
	System	12 Feb 2021 18:08:43

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-12T12:05:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '00ef3c93-ccc8-456a-a1ec-cbf86ff6c80e' User entered 'No (N)'	System	12 Feb 2021 18:08:43

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-12T12:06:03', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '00ef3c93-ccc8-456a-a1ec-cbf86ff6c80e' User entered '12 Feb 2021 12:06:03'	System	12 Feb 2021 18:08:43
	System	12 Feb 2021 18:08:43

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-18T10:19:59', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd63f55be-7485-4dd6-b977-a9f00f136632'	System	18 Feb 2021 16:20:10
User entered 'No (N)'	System	18 Feb 2021 16:20:10

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-18T10:20:03', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd63f55be-7485-4dd6-b977-a9f00f136632'	System	18 Feb 2021 16:20:10
User entered 'No (N)'	System	18 Feb 2021 16:20:10

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-18T10:20:07', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'd63f55be-7485-4dd6-b977-a9f00f136632'	System	18 Feb 2021 16:20:10
User entered '18 Feb 2021 10:20:07'	System	18 Feb 2021 16:20:10

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-24T16:49:30-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e1c6b808-af0d-4cd9-a3b6-203d41f006c6'	System	02 Mar 2021 17:12:26
User entered 'No (N)'	System	02 Mar 2021 17:12:26

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-24T16:49:33-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e1c6b808-af0d-4cd9-a3b6-203d41f006c6'	System	02 Mar 2021 17:12:26
User entered 'No (N)'	System	02 Mar 2021 17:12:26



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-02-24T16:49:37-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'e1c6b808-af0d-4cd9-a3b6-203d41f006c6' User entered '24 Feb 2021 21:49:37'	System	02 Mar 2021 17:12:26
	System	02 Mar 2021 17:12:26

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-03T06:54:40-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c763b10-44e4-49c4-8eec-1aeff6d08c10'	System	03 Mar 2021 12:55:03
User entered 'No (N)'	System	03 Mar 2021 12:55:03

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-03T06:54:55-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c763b10-44e4-49c4-8eec-1aeff6d08c10'	System	03 Mar 2021 12:55:03
User entered 'No (N)'	System	03 Mar 2021 12:55:03

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-03T06:54:59-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '2c763b10-44e4-49c4-8eec-1aeff6d08c10'	System	03 Mar 2021 12:55:03
User entered '03 Mar 2021 06:54:59'	System	03 Mar 2021 12:55:03

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-13T17:38:07-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '25f44ccd-7f5b-4f76-8954-d551e59e683b'	System	13 Mar 2021 23:38:22
User entered 'No (N)'	System	13 Mar 2021 23:38:22

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-13T17:38:14-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '25f44ccd-7f5b-4f76-8954-d551e59e683b'	System	13 Mar 2021 23:38:22
User entered 'No (N)'	System	13 Mar 2021 23:38:22

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-13T17:38:18-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '25f44ccd-7f5b-4f76-8954-d551e59e683b'	System	13 Mar 2021 23:38:22
User entered '13 Mar 2021 17:38:18'	System	13 Mar 2021 23:38:22

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-18T04:09:36-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'bb86571a-1710-496e-bcda-d7c8971c28e6'	System	18 Mar 2021 09:09:50
User entered 'No (N)'	System	18 Mar 2021 09:09:50

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-18T04:09:42-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'bb86571a-1710-496e-bcda-d7c8971c28e6'	System	18 Mar 2021 09:09:50
User entered 'No (N)'	System	18 Mar 2021 09:09:50

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-18T04:09:47-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'bb86571a-1710-496e-bcda-d7c8971c28e6'	System	18 Mar 2021 09:09:50
User entered '18 Mar 2021 04:09:47'	System	18 Mar 2021 09:09:50

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-24T17:25:03-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4cd3e1a8-fbf4-45f1-903f-2413f9143521' User entered 'No (N)'	System	24 Mar 2021 22:25:19
	System	24 Mar 2021 22:25:19

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-24T17:25:09-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4cd3e1a8-fbf4-45f1-903f-2413f9143521'	System	24 Mar 2021 22:25:19
User entered 'No (N)'	System	24 Mar 2021 22:25:19



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-24T17:25:13-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4cd3e1a8-fbf4-45f1-903f-2413f9143521' User entered '24 Mar 2021 17:25:13'	System	24 Mar 2021 22:25:19
	System	24 Mar 2021 22:25:19

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-31T16:31:14-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a39e23e8-8727-4ee5-b483-5e8384231ee1' User entered 'No (N)'	System	31 Mar 2021 21:31:30
	System	31 Mar 2021 21:31:30

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-31T16:31:22-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a39e23e8-8727-4ee5-b483-5e8384231ee1' User entered 'No (N)'	System	31 Mar 2021 21:31:30
	System	31 Mar 2021 21:31:30

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-31T16:31:26-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'a39e23e8-8727-4ee5-b483-5e8384231ee1' User entered '31 Mar 2021 16:31:26'	System	31 Mar 2021 21:31:30
	System	31 Mar 2021 21:31:30

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-08T13:48:27-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c1fc580c-ac8a-4b15-8f49-412ced853a06'	System	08 Apr 2021 18:48:39
User entered 'No (N)'	System	08 Apr 2021 18:48:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-08T13:48:32-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c1fc580c-ac8a-4b15-8f49-412ced853a06'	System	08 Apr 2021 18:48:39
User entered 'No (N)'	System	08 Apr 2021 18:48:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-08T13:48:36-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: 'c1fc580c-ac8a-4b15-8f49-412ced853a06'	System	08 Apr 2021 18:48:39
User entered '08 Apr 2021 13:48:36'	System	08 Apr 2021 18:48:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-23T14:33:41-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4e36b68d-8a60-4012-845b-e63b89734733'	System	23 Apr 2021 19:33:52
User entered 'No (N)'	System	23 Apr 2021 19:33:52

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-23T14:33:47-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4e36b68d-8a60-4012-845b-e63b89734733'	System	23 Apr 2021 19:33:52
User entered 'No (N)'	System	23 Apr 2021 19:33:52

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-23T14:33:50-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4e36b68d-8a60-4012-845b-e63b89734733'	System	23 Apr 2021 19:33:52
User entered '23 Apr 2021 14:33:50'	System	23 Apr 2021 19:33:52

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-30T12:29:25-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4dc2e998-6cf4-45aa-ae6e-7775d53e2de1' User entered 'No (N)'	System	30 Apr 2021 17:29:39
	System	30 Apr 2021 17:29:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Have you been exposed to someone with 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 (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-30T12:29:31-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4dc2e998-6cf4-45aa-ae6e-7775d53e2de1' User entered 'No (N)'	System	30 Apr 2021 17:29:39
	System	30 Apr 2021 17:29:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-04-30T12:29:35-05:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '4dc2e998-6cf4-45aa-ae6e-7775d53e2de1' User entered '30 Apr 2021 12:29:35'	System	30 Apr 2021 17:29:39
	System	30 Apr 2021 17:29:39

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:17:28



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:17:28



**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:17:28

**US3012096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:53:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:17:28
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:17:28

US3012096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-02T11:04:21-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '7d9cca17-0ef0-4c49-b5f6-40c3b6078f83'	System	02 Mar 2021 17:13:03
User entered 'Yes (Y)'	System	02 Mar 2021 17:13:03

US3012096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:21

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-02T11:04:27-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '7d9cca17-0ef0-4c49-b5f6-40c3b6078f83'	System	02 Mar 2021 17:13:03
User entered 'No (N)'	System	02 Mar 2021 17:13:03

**US3012096**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8DB033C-5C91-49CE-9D1F-319B4994E599)', Time: '2021-03-02T11:04:32-06:00', User OID: 'PatientReportedOutcome (US3012096)', ODM File OID: '7d9cca17-0ef0-4c49-b5f6-40c3b6078f83'	System	02 Mar 2021 17:13:03
User entered '02 Mar 2021 11:04:32'	System	02 Mar 2021 17:13:03

**US3012096**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:24:31
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	03 Nov 2020 19:33:44
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:24:31
User entered '3 Nov 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	03 Nov 2020 19:33:44

**US3012096**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:24:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Katherine Davis (b) (4) (b) (4)	03 Nov 2020 19:33:44



**US3012096**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:24:31
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	03 Nov 2020 19:33:44
	(b) (4)	

US3012096

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:24:31
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	03 Nov 2020 19:33:49
	(b) (4)	

**US3012096**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:04:06
User entered 'I'	(b) (4), (b) (6) System	03 Nov 2020 19:33:49

**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	07 Dec 2020 23:38:05

**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '07 Dec 2020'	Jennifer Leyva (b) (4)	07 Dec 2020 23:38:05

**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Contact Made (CONTACT MADE)'	Jennifer Leyva (b) (4)	07 Dec 2020 23:38:05

**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Jennifer Leyva (b) (4)	07 Dec 2020 23:38:05

**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	07 Dec 2020 23:38:08



**US3012096**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User entered 'I'	System	07 Dec 2020 23:38:08

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 18:45:07

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '5 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 18:45:07

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 18:45:07

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 18:45:07

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 18:45:11

**US3012096**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User entered 'I'	System	05 Jan 2021 18:45:11

**US3012096**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Katherine Davis (b) (4)	05 Feb 2021 23:53:25



**US3012096**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '5 Feb 2021'	Katherine Davis (b) (4)	05 Feb 2021 23:53:25

**US3012096**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	05 Feb 2021 23:53:25

US3012096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Katherine Davis (b) (4)	05 Feb 2021 23:53:25

US3012096

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Katherine Davis (b) (4)	05 Feb 2021 23:53:31

**US3012096**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:36:07
User entered 'I'	System	05 Feb 2021 23:53:31

US3012096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	09 Mar 2021 00:14:57
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '08 Mar 2021'	Pamela Fidler (b) (4)	09 Mar 2021 00:14:57

US3012096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	09 Mar 2021 00:14:57
	(b) (4)	
	(b) (4)	



**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'VISIT4'	System	09 Mar 2021 00:14:57

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '08 Mar 2021'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '14:15'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered '08 Mar 2021 14:15'	System	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '98.4' F	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04



**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '85'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'bpm'	System	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '14'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'breaths/min'	System	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '135'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'mmHg'	System	31 Mar 2021 21:14:04

US3012096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '73'	Jennifer Leyva (b) (4)	31 Mar 2021 21:14:04

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'mmHg'	System	31 Mar 2021 21:14:04



**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:53:21**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31

US3012096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4)	09 Mar 2021 00:15:05
	Pamela Fidler (b) (4)	
	(b) (4)	
	(b) (4)	

US3012096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Pamela Fidler (b) (4)	09 Mar 2021 00:15:05

US3012096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	09 Mar 2021 00:15:16

US3012096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '08 Mar 2021'	Pamela Fidler (b) (4)	09 Mar 2021 00:15:16
	(b) (4)	
	(b) (4)	

US3012096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '14:25'	Pamela Fidler (b) (4)	09 Mar 2021 00:15:16

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered '08 Mar 2021 14:25'	System	09 Mar 2021 00:15:16



US3012096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	09 Mar 2021 00:15:19

**US3012096**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:31
User entered 'I'	System	09 Mar 2021 00:15:19

**US3012096**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	05 Apr 2021 23:24:35

**US3012096**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '5 Apr 2021'	Jessica Ruff (b) (4)	05 Apr 2021 23:24:35

**US3012096**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:53:21**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4)	05 Apr 2021 23:24:35

US3012096

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	Jessica Ruff (b) (4)	05 Apr 2021 23:24:35

US3012096

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	05 Apr 2021 23:24:37

**US3012096**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:47:45
User entered 'I'	System	05 Apr 2021 23:24:37



US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '22 Jan 2021'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:21

[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 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:53:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	25 Jan 2021 19:06:03

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '22 Jan 2021'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:53:21**

[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 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:39:12
	(b) (4)	
User entered '0'	Pamela Fidler (b) (4)	08 Apr 2021 17:55:35
	(b) (4)	
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:40:48

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		13 Apr 2021 02:15:13
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:39:12
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated' (Site from DM).	(b) (4)	
	Pamela Fidler (b) (4)	08 Apr 2021 17:55:56
	(b) (4)	
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Pamela Fidler (b) (4)	08 Apr 2021 17:55:35
	(b) (4)	
	(b) (4)	
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:19:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:40:48



US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '22 Jan 2021'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:53:21**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'No (N)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:22
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:53:21**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User entered empty.	(b) (4), (b) (6) System	25 Jan 2021 19:06:22

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:53:21**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User entered empty.	(b) (4), (b) (6) System	25 Jan 2021 19:06:22

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:39
	(b) (4)	
	(b) (4)	



US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '22 Jan 2021'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:39
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '10:12'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:39
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:53:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User entered '22 Jan 2021 10:12'	(b) (4), (b) (6) System	25 Jan 2021 19:06:39

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:51
	(b) (4)	
	(b) (4)	

US3012096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '22 Jan 2021'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:51
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:53:21**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '10:04'	Pamela Fidler (b) (4)	25 Jan 2021 19:06:51
	(b) (4)	
	(b) (4)	

**US3012096**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:53:21**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:04
User entered '22 Jan 2021 10:04'	(b) (4), (b) (6) System	25 Jan 2021 19:06:51

US3012096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:53:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:29
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
	(b) (4)	
Signature has been broken.	Jessica Ruff (b) (4)	05 Apr 2021 21:27:30
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Jessica Ruff (b) (4)	05 Apr 2021 21:27:30
	(b) (4)	
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:32:51
	(b) (4)	
User entered 'No (N)'	Jennifer Leyva (b) (4)	08 Sep 2020 20:13:20
	(b) (4)	



**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:36:13
User entered		
'USA-US006-2021-mRNA-1273-P301000008'	System	06 Apr 2021 18:36:08
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 18:36:08

US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Medical record indicates medical history of ischemic colitis and is questionable for history of Crohn's disease. Consider revising this event to a worsening of a pre-existing condition of ischemic colitis or worsening of pre-existing Crohn's?' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:03
Query 'PV Query: Medical record indicates medical history of ischemic colitis and is questionable for history of Crohn's disease. Consider revising this event to a worsening of a pre-existing condition of ischemic colitis or worsening of pre-existing Crohn's?' answered with 'Per PI, new diagnosis of Crohns should stand' (Site from Safety).	Jennifer Leyva (b) (4)	29 Apr 2021 16:39:21
User opened query 'PV Query: Medical record indicates medical history of ischemic colitis and is questionable for history of Crohn's disease. Consider revising this event to a worsening of a pre-existing condition of ischemic colitis or worsening of pre-existing Crohn's?' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:32:32
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Crohn's disease, LLT: Crohn's disease - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 21:56:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 21:56:47
Data point term sent to Coder	System	05 Apr 2021 21:47:24
User entered 'Crohn's Disease'	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'No (N)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'No (N)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '3 Nov 2020'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:47:08



US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). Signature has been broken.	(b) (4) System	29 Apr 2021 16:42:49
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4) Jennifer Leyva (b) (4) (b) (4)	29 Apr 2021 16:42:49
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 16:40:37
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)	14 Apr 2021 14:03:24
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 'Pending follow-up' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 14:22:30
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)	12 Apr 2021 21:01:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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)	29 Apr 2021 19:53:05
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
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.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:54
Signature has been broken.	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User entered '27 Apr 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
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)	29 Apr 2021 16:35:08
User closed 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)	21 Apr 2021 20:08:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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' answered with 'Pt just began medication to treat condition. No update/resolution expected soon. Against site policy to leave queries open as they are counted against site compliance. Will update at next contact with subject.' (Site from Safety).	Jennifer Leyva (b) (4)	21 Apr 2021 15:04:34
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)	19 Apr 2021 19:20:56
User closed 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).		19 Apr 2021 19:20:56
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.' answered with 'We do not leave queries open we will update when information becomes available' (Site from Safety).	Pamela Fidler (b) (4)	16 Apr 2021 14:30:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	14 Apr 2021 16:02:42
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	(b) (4) Jessica Ruff (b) (4)	05 Apr 2021 21:47:08
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User closed 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)	14 Apr 2021 14:03:35
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. ' answered with 'Pending update. Currently correct as entered' (Site from Safety).	Jennifer Leyva (b) (4)	13 Apr 2021 14:22:52
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)	12 Apr 2021 21:01:22
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Please report AE as SAE due to hospitalization.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:20:17
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Query 'Please report AE as SAE due to hospitalization.' answered with '"Is the adverse event serious?" is marked Yes	Jennifer Leyva (b) (4)	06 Apr 2021 14:54:52
' (Site from CRA).	(b) (4)	
User opened query 'Please report AE as SAE due to hospitalization.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 14:37:01
User entered 'I'	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Medical record indicates hospital admission date to be 04 Nov 2020. Please consider revising admission date.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:07
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
Query 'PV Query: Medical record indicates hospital admission date to be 04 Nov 2020. Please consider revising admission date.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	29 Apr 2021 16:41:15
Signature has been broken.	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User entered '04 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User opened query 'PV Query: Medical record indicates hospital admission date to be 04 Nov 2020. Please consider revising admission date.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:33:26
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '3 Nov 2020'	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Medical record indicates hospital discharge date to be 07 Nov 2020. Please consider revising hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:09
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
Query 'PV Query: Medical record indicates hospital discharge date to be 07 Nov 2020. Please consider revising hospital discharge date.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	29 Apr 2021 16:41:30
Signature has been broken.	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User entered '07 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User opened query 'PV Query: Medical record indicates hospital discharge date to be 07 Nov 2020. Please consider revising hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:32:57
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '6 Nov 2020'	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:52:45
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	06 Apr 2021 14:54:12
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending medical records' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	06 Apr 2021 14:53:17
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 21:47:08
User entered 'Unknown (UNK)'	Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	06 Apr 2021 14:55:19
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	06 Apr 2021 14:55:19
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	06 Apr 2021 14:55:19
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	06 Apr 2021 14:54:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Apr 2021 14:54:12
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	06 Apr 2021 14:54:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Apr 2021 21:47:08
User entered 'UNK' (non-conformant).	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '1'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Outcome](#)

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. Please leave query open until information is available.	(b) (4), (b) (6)	29 Apr 2021 19:53:11
' (Site from Safety).		
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
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. Please leave query open until information is available.	(b) (4) Jennifer Leyva (b) (4)	29 Apr 2021 16:41:51
' answered with 'Updated' (Site from Safety).		
Signature has been broken.	Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4) Jennifer Leyva (b) (4)	29 Apr 2021 16:40:37
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. Please leave query open until information is available.	(b) (4), (b) (6)	29 Apr 2021 16:34:26
' (Site from Safety).		

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:53:21

[Outcome](#)

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. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:08:30
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. Please leave query open until information is available' answered with 'Pt just began medication to treat condition. No update/resolution expected soon. Against site policy to leave queries open as they are counted against site compliance. Will update at next contact with subject.' (Site from Safety).	Jennifer Leyva (b) (4)	21 Apr 2021 15:04:48
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. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:20:45
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:20:45

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[Outcome](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' answered with 'It is not resolved per our narrative. Started a new med on 27MAR2021 We will update more as we assess ' (Site from Safety).	Pamela Fidler (b) (4) (b) (4) (b) (4)	16 Apr 2021 14:36:29
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:04:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:50:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	29 Apr 2021 17:26:49
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
Signature has been broken.	System	29 Apr 2021 16:42:21
	Jennifer Leyva (b) (4)	29 Apr 2021 16:42:21
User entered 'Ongoing symptoms' reason for change: Data Entry Error	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	Jennifer Leyva (b) (4)	29 Apr 2021 16:42:21
	(b) (4)	
User signature succeeded.	System	29 Apr 2021 16:40:37
	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
	(b) (4)	
User entered empty.	Jessica Ruff (b) (4)	05 Apr 2021 21:47:08
	(b) (4)	

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[Narrative](#)

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. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:09:12
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. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:08:55
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. Please leave query open until information is available' answered with 'Hospital records requested x3. No more attempts to retrieve will be made.' (Site from Safety).	Jennifer Leyva (b) (4)	20 Apr 2021 14:01:27
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. Please leave query open until information is available' answered with 'Hospital records requested x3. No more attempts to retrieve will be made.' (Site from Safety).	Jennifer Leyva (b) (4)	20 Apr 2021 14:01:15
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. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:20:36

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[Narrative](#)

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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:20:36
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. Please leave query open until information is available' (Site from Safety).		19 Apr 2021 19:20:27
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. Please leave query open until information is available.' (Site from Safety).		19 Apr 2021 19:20:27
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. Please leave query open until information is available.' answered with 'Against site policy to keep queries open as it is counted against the site We will send when updates and medical records are received.' (Site from Safety).	Pamela Fidler (b) (4) (b) (4) (b) (4)	16 Apr 2021 14:52:08
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. Please leave query open until information is available.' answered with 'Against site policy to keep queries open as it is counted against the site,. Will update when information is available' (Site from Safety).	Pamela Fidler (b) (4) (b) (4) (b) (4)	16 Apr 2021 14:51:35

US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:03:29
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. Please leave query open until information is available.' (Site from Safety).		14 Apr 2021 16:02:06
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).		14 Apr 2021 14:03:54
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).		14 Apr 2021 14:03:46
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 'Records pending. 3 request attempts made.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 14:23:40

US3012096

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:21

[Narrative](#)

Audit	User	Time (GMT)
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 'Records pending. 3 request attempts made.' (Site from Safety).	Jennifer Leyva (b) (4)	13 Apr 2021 14:23:27
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)	12 Apr 2021 21:01:29
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).		12 Apr 2021 21:01:07
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Site made aware of SAE on 05-APR-2021 during Day 239 Safety Call when querying subject about new medications. Subject sought medical attention for abdominal pain on 03-NOV-2021. Subject was admitted to hospital on 03-NOV-2021 and diagnosed with Crohn's Disease, discharged from hospital 06-NOV-2021. Medical records requested, pending receipt for additional information and medications. Per PI, SAE not related to IP or study procedure. Con-med (Humira) started for management of SAE on 27-MAR-2021. Currently ongoing/not resolved.'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 21:47:08



**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:47:08

**US3012096**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 21:47:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:53:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:29
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 02:14:48
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Per safety call patient incorrectly marked yes ' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	23 Mar 2021 18:57:43
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:56:27
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:23
Data point term sent to Coder	System	27 Aug 2020 15:21:20
User entered 'duloxetine'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'depression'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '60'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2014'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:20:39

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:20:39

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:53
Data point term sent to Coder	System	27 Aug 2020 15:28:35
User entered 'lisinopril'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'hypertension'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '40'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2012'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:28:08

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:28:08



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:28:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:02
Data point term sent to Coder	System	27 Aug 2020 15:29:40
User entered 'amlodipine'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'hypertension'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '5'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	27 Aug 2020 15:29:27
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	27 Aug 2020 15:29:00
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty; reason for change Data Entry Error	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:29:27
User entered 'o'	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:29:00
	(b) (4)	



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 15:29:27
User entered 'Oral (ORAL)' reason for change: Data Entry Error	System	27 Aug 2020 15:29:27
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Leyva (b) (4)	27 Aug 2020 15:29:27
User entered empty.	(b) (4)	
	System	27 Aug 2020 15:29:00
	Jennifer Leyva (b) (4)	27 Aug 2020 15:29:00
	(b) (4)	

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	27 Aug 2020 15:29:27
	(b) (4)	
User entered 'u'	Jennifer Leyva (b) (4)	27 Aug 2020 15:29:00
	(b) (4)	

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	27 Aug 2020 15:29:27
User entered 'UN UNK 2012' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 15:29:00
User entered '20 ' (non-conformant).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:29:00



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:29:00

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:29:00

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 07:50:13
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'MEDICATION HAS TWO DIFFERENT DOSAGES - ONE TAKEN AM, THE OTHER TAKEN PM - DOSAGES (MG) HAVE BEEN UPDATED' (Site from DM).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:22:35
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:55:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: ZIPRASIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 20:24:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 20:24:51
Data point term sent to Coder	System	27 Aug 2020 15:30:41
User entered 'ziprasidone'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'bipolar depression'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered '40' reason for change: Data Entry Error	Lamar Box (b) (4)	18 Sep 2020 20:21:24
	(b) (4)	
User entered '160'	Jennifer Leyva (b) (4)	27 Aug 2020 15:30:13
	(b) (4)	

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 15:32:13
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	27 Aug 2020 15:32:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Aug 2020 15:30:13
	Jennifer Leyva (b) (4)	27 Aug 2020 15:30:13
	(b) (4)	

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:30:13
	(b) (4)	



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

US3012096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2017'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:13



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:30:13
	(b) (4)	

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:30:13

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:30:13

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 07:50:34
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:22:58
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:54:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: ZIPRASIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 20:24:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 20:24:50
Data point term sent to Coder	System	27 Aug 2020 15:31:44
User entered 'ziprasidone'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'bipolar depression'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '160'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2017'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:30:50

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:30:50

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:25:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:25:47
Data point term sent to Coder Coding entries removed.	System Lamar Box (b) (4)	18 Sep 2020 20:24:49 18 Sep 2020 20:24:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:28:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:28:21
Data point term sent to Coder User entered 'omeprazole'	System Jennifer Leyva (b) (4)	27 Aug 2020 15:31:45 27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 07:51:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'DATA CORRECTED' (Site from DM).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:24:46
User entered 'GERD' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:24:30
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:30:34
User entered 'acid reflux'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '40'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2017'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:31:09

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:31:09



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:28:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:22
Data point term sent to Coder	System	27 Aug 2020 15:31:46
User entered 'atorvastatin'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'hypercholesterolemia'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '20'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2018'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:31:45



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:31:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:31:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 00:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:48:57
Data point term sent to Coder	System	27 Aug 2020 15:44:13
User entered 'tizanidine'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 07:53:40
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MEDICAL HISTORY UPDATED' (Site from DM).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:33:43
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:36:44
User entered 'back spasms'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '4'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:43:58
	(b) (4)	



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'three times daily (TID)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2018'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:43:58

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:43:58

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:29:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:29:42
Data point term sent to Coder	System	27 Aug 2020 15:46:15
User entered 'metformin'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'diabetes, type ii'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '500'	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:45:52



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'twice daily (BID)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

US3012096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2010'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:45:52

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:45:52

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:28:36
Data point term sent to Coder Coding entries removed.	System Lamar Box (b) (4)	18 Sep 2020 20:27:54 18 Sep 2020 20:27:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 09:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 09:44:42
Data point term sent to Coder User entered 'gabapentin'	System Jennifer Leyva (b) (4)	27 Aug 2020 15:47:18 27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please update the indication and clarify the type of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). Query 'Per DM CLR: Please update the indication and clarify the type of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 07:54:03
User entered 'NEUROPATHY, BILATERAL FEET' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:27:24
User opened query 'Per DM CLR: Please update the indication and clarify the type of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:49:07
User entered 'neuropathy, feet'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '800'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated for reported dose. Please update the Frequency as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 09:11:02
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated for reported dose. Please update the Frequency as appropriate.' answered with 'This is as advised by the patient' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	13 Oct 2020 14:47:47
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated for reported dose. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:01:47
User entered 'four times daily (QID)'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2017'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:46:30

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:46:30



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
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/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 00:05:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 00:05:53
Data point term sent to Coder Coding entries removed.	System Jennifer Leyva (b) (4)	22 Sep 2020 00:05:11 22 Sep 2020 00:05:06
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/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:56
Data point term sent to Coder User entered 'hydrocodone/APAP'	System Jennifer Leyva (b) (4)	27 Aug 2020 15:48:22 27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 07:30:21
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:05:11
User entered 'PAIN, BACK AND FEET, due to neuropathy' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:05:06
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 06:30:31
User entered 'pain, back and feet'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '10/325'	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:47:26
	(b) (4)	

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'four times daily (QID)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2014'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Aug 2020 15:47:26



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:47:26

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:47:26

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:10:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:10:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:07:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:07:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:57
Data point term sent to Coder	System	27 Aug 2020 15:48:22
User entered 'fluticasone'	Jennifer Leyva (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'seasonal allergies'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'I'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'spray'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:48:10

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:48:10

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:30:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:30:01
Data point term sent to Coder	System	27 Aug 2020 15:49:25
User entered 'Vitamin D3'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 06:17:02
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 23:58:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 23:58:45
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:41:06
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'nutritional supplement'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '2000'	(b) (4) Jennifer Leyva (b) (4)	27 Aug 2020 15:48:38
	(b) (4)	



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'IU (IU)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN May 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:48:38

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:48:38

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:29:58
Data point term sent to Coder	System	27 Aug 2020 15:49:27
User entered 'benadryl'	Jennifer Leyva (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'seasonal allergies'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '25'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	27 Aug 2020 15:51:14
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	27 Aug 2020 15:49:16
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	27 Aug 2020 15:51:14
	(b) (4)	
User entered 'o'	Jennifer Leyva (b) (4)	27 Aug 2020 15:49:16
	(b) (4)	

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'UN UNK 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:49:16

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:49:16



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
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/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:16:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:16:44
Data point term sent to Coder	System	18 Sep 2020 20:15:28
User entered 'HYDROCODONE/APAP'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE 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 of 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 09:11:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE 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 of 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'Reported on Day 2 of Diary Dose 2' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 18:52:10

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

[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 timeframe. If the PAIN AT INJECTION SITE 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 of 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:23:52
User entered 'PAIN AT INJECTION SITE'	Lamar Box (b) (4) (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'I'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'tablet (TABLET)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once daily (QD)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Oral (ORAL)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '9 Sep 2020'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '9 Sep 2020'	Lamar Box (b) (4)	18 Sep 2020 20:14:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Lamar Box (b) (4)	18 Sep 2020 20:14:45



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User entered '1'	System	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User entered '1'	System	18 Sep 2020 20:14:45

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:19
User entered '804 (804)'	System	18 Sep 2020 20:14:45

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
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)	07 Oct 2020 15:09:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:09:12
Data point term sent to Coder	System	07 Oct 2020 13:18:28
User entered 'influenza vaccine'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Yes (Y)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'influenza prevention'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0.5'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'mL (mL)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25



US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'once (ONCE)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'Intramuscular (INTRAMUSCULAR)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered empty.	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '1 Oct 2020'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '0'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered '1 Oct 2020'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	Tambra Dora (b) (4)	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User entered empty.	System	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User entered empty.	System	07 Oct 2020 13:18:25

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:27
User entered empty.	System	07 Oct 2020 13:18:25

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS, PRODUCT: ADALIMUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 00:10:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 00:10:42
Data point term sent to Coder	System	05 Apr 2021 23:26:25
User entered 'Adalimumab'	Jessica Ruff (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'No (N)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Crohn's Disease (AE #1)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '40'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'mg (mg)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'other (OTHER)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Every 2 weeks'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

US3012096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '27 Mar 2021'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14



**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '0'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'Yes (Y)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered empty.	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'No (N)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 23:26:14

**US3012096**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:53:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 23:26:14

US3012096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:53:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:20:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:49:12
User entered 'No (N)'	Jennifer Leyva (b) (4)	27 Aug 2020 15:51:22



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'USA-US006-2021-MRNA-1273-P301000008'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Laurence'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Chu'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '3100 Red River Street'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Austin'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'TX'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '78705'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:53:45
DataPoint Verified.		14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'US'	(b) (4) System	06 Apr 2021 18:36:54

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:53:37
User entered '1'	System	06 Apr 2021 18:36:54



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'USA-US006-2021-MRNA-1273-P301000008'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Laurence'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Chu'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '3100 Red River Street'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Austin'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'TX'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '78705'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:53:45
DataPoint Verified.		14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'US'	(b) (4) System	06 Apr 2021 18:36:54

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:53:37
User entered '1'	System	06 Apr 2021 18:36:54



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:53:21**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '06/Apr/2021 11:36'	(b) (4) System	06 Apr 2021 18:36:54

US3012096

Folder: SAE USA-US006-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:21

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:53:45
DataPoint Verified.		14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:54
User entered '0'		06 Apr 2021 18:36:40

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'USA-US006-2021-MRNA-1273-P301000008'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Yes (Y)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'No (N)'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Laurence'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Chu'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '3100 Red River Street'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'Austin'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered 'TX'	System	06 Apr 2021 18:36:08

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:34
User entered '78705'	System	06 Apr 2021 18:36:08



**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:53:45
DataPoint Verified.		14 Apr 2021 22:21:36
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:50:25
User entered 'US'	(b) (4) System	06 Apr 2021 18:36:54

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:53:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:53:37
User entered '1'	System	06 Apr 2021 18:36:54

**US3012096**

**Folder: SAE USA-US006-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:53:21**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:07
User entered '29/Apr/2021 15:53'	(b) (4) System	29 Apr 2021 19:53:37

US3012096

Folder: SAE USA-US006-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:21

**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.	Laurence Chu (b) (4)	30 Apr 2021 15:32:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:53:45
User entered 'I'		29 Apr 2021 19:53:37