

US3622160 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:13:29

All time stamps listed in this document are displayed in GMT

US3622160

Form: Participant Creation

Data signed: (b) (4) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

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[Participant ID](#)

US3622160

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

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US3622160

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	SCRN

US3622160

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

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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) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

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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 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	HIV INFECTION
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
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 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	CORONARY ARTERY DISEASE
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 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	DIABETES
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 (7)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	EMPHYSEMA
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 (8)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	ACUTE CORONARY SYNDROME
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 (13)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	ANGINA
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 (14)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	PERIPHERAL NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN UNK 2010
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	CHRONIC ARTHRITIS (RHEUMATOID)
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Condition	POST MENOPAUSE
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)	_____

US3622160

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	5 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:15 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 11:15
Height ( <i>xxx.x</i> )	55 in
Weight ( <i>xxx.x</i> )	156 lb
BMI ( <i>xxx.x</i> )	36.33366 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)	

US3622160

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 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) 26 Sep 2020 13:02:27

Generated On: 10 Jun 2021 09:13:29

Date of assessment (*dd MMM yyyy*) 5 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2017

Date of last menstruation unknown False

US3622160

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

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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**

DISABLED, SOCIALLY ACTIVE

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

<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)	True
<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) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

What was the date of randomization? (dd MMM yyyy) 05 SEP 2020

What was the participant's randomization number? 145570

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 ☐



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 26 Sep 2020 13:02:28**

**Generated On: 10 Jun 2021 09:13:29**

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) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

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)	5 SEP 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 11:15
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

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)	5 SEP 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 13:29
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

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) 13 Sep 2020 16:35:29

Generated On: 10 Jun 2021 09:13:29

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) 5 SEP 2020

What was the treatment time? (00:00-23:59) 12:54 (24 HR)

Treatment Date and Time (derived) 5 SEP 2020 12:54

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) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 SEP 2020
Collection time (00:00-23:59)	11:30 (24 HR)
Collection date and time (derived)	5 SEP 2020 11:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

Collection date (dd MMM yyyy)			5 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	5 SEP 2020 11:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 13:02:28

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**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

98.7 °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

05 SEP 2020 13:29

PC Open Date & Time

05 SEP 2020 13:14

PC Close Date & Time

05 SEP 2020 15:44

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**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	05 SEP 2020 21:52
PC Open Date & Time	05 SEP 2020 16:39
PC Close Date & Time	06 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 06 SEP 2020 12:19

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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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 ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 07 SEP 2020 12:17

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PC Open Date & Time 07 SEP 2020 12:00

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PC Close Date & Time 08 SEP 2020 11:59

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US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 19:46

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 19:19

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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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 ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 10 SEP 2020 18:20

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

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US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 11 SEP 2020 17:49

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**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

05 SEP 2020 13:29

PC Open Date & Time

05 SEP 2020 13:14

PC Close Date & Time

05 SEP 2020 15:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**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

05 SEP 2020 21:53

PC Open Date & Time

05 SEP 2020 16:39

PC Close Date & Time

06 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**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

06 SEP 2020 12:20

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**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

07 SEP 2020 12:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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

08 SEP 2020 19:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**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

09 SEP 2020 19:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

**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

10 SEP 2020 18:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**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

11 SEP 2020 17:49

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**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 ☐

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 13:30
PC Open Date & Time	05 SEP 2020 13:14
PC Close Date & Time	05 SEP 2020 15:44

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**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 ☐

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 21:53
PC Open Date & Time	05 SEP 2020 16:39
PC Close Date & Time	06 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:19
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:18
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 ☒

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 ☒

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EAB) (1725)

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 17:50
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59



US3622160

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 13:02:27

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 13:02:27

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 13:40:14

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:40:14

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	VISIT2

US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

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)	3 OCT 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	3 OCT 2020 10:26
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG



US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

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)	3 OCT 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	3 OCT 2020 12:30
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3622160

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 OCT 2020

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

US3622160

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

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) 3 OCT 2020

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 3 OCT 2020 11:49

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

What was the frequency of the study treatment dosing? ONCE

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

US3622160

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 OCT 2020

Collection time (00:00-23:59)

10:45 (24 HR)

Collection date and time (derived)

3 OCT 2020 10:45

US3622160

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Collection date (dd MMM yyyy)			3 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	3 OCT 2020 10:40
Nasopharyngeal Swab 2	No		

US3622160

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:40:45

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**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

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

03 OCT 2020 12:27

PC Open Date & Time

03 OCT 2020 12:09

PC Close Date & Time

03 OCT 2020 14:39

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	03 OCT 2020 22:47
PC Open Date & Time	03 OCT 2020 15:34
PC Close Date & Time	04 OCT 2020 11:59



US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 04 OCT 2020 22:17

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 21:43

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 07 OCT 2020 01:23

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 08 OCT 2020 08:00

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PC Open Date & Time 07 OCT 2020 12:00

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PC Close Date & Time 08 OCT 2020 11:59

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US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

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 OCT 2020 19:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:27

PC Open Date & Time

03 OCT 2020 12:09

PC Close Date & Time

03 OCT 2020 14:39

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**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

03 OCT 2020 22:47

PC Open Date & Time

03 OCT 2020 15:34

PC Close Date & Time

04 OCT 2020 11:59



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**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

04 OCT 2020 22:17

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**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

05 OCT 2020 21:44

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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

07 OCT 2020 01:23

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**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

08 OCT 2020 08:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

**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

08 OCT 2020 19:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**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 ☐

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 12:28
PC Open Date & Time	03 OCT 2020 12:09
PC Close Date & Time	03 OCT 2020 14:39



US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**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 ☐

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 22:48
PC Open Date & Time	03 OCT 2020 15:34
PC Close Date & Time	04 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:18
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 21:45
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**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)

110 of 2192

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 01:24
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59



US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 08:00
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

**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 ☒

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 19:01
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**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 ☐

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3622160

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 20:02:27

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:02:27

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3622160

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 14:57:27

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 14:57:27

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:29:38

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:29:38

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 16:29:39

Generated On: 10 Jun 2021 09:13:29

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

Visit date (dd MMM yyyy)	29 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3622160

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 16:29:39

Generated On: 10 Jun 2021 09:13:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:40
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622160

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 16:29:39

Generated On: 10 Jun 2021 09:13:29

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.*

US3622160

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 16:29:39

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

10:55 (24 HR)

Collection date and time (derived)

29 OCT 2020 10:55



US3622160

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:29:39

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3622160

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

13 NOV 2020 16:47:02

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3622160

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

19 NOV 2020 14:27:25

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:30:56

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 09:20:10

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission 18 DEC 2020 16:10:01

Patient Cloud Open Date & Time 14 DEC 2020 00:01

Patient Cloud Close Date & Time 18 DEC 2020 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

22 DEC 2020 15:36:55

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

29 DEC 2020 11:34:24

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 00:33:49
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

11 JAN 2021 19:55:34

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

18 JAN 2021 09:44:52

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

25 JAN 2021 13:22:34

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59



US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 08:29:04

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

08 FEB 2021 09:42:15

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

16 FEB 2021 21:39:08

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

25 FEB 2021 11:58:00

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

01 MAR 2021 09:46:30

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

09 MAR 2021 07:46:28

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

15 MAR 2021 16:03:10

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

23 MAR 2021 16:15:01

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59



US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

29 MAR 2021 18:42:20

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

09 APR 2021 10:36:53

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

15 APR 2021 12:01:13

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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

20 APR 2021 07:47:58

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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26 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 APR 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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19 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUL 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

26 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59



US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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°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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 SEP 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59



US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

27 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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22 OCT 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2021 23:59
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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59
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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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°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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 FEB 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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22 APR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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29 APR 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐  
Yes ☐

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

27 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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"/>

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐  
Yes ☐

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

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29 JUL 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2022 23:59

US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

**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 ☐

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2022 23:59

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US3622160

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

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

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

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**US3622160**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:13:29**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 09:46:44

US3622160

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3622160

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:05:47

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:56:18

Generated On: 10 Jun 2021 09:13:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622160

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:56:18

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622160

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3622160

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 APR 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 09:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622160

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

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.*

US3622160

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	9 APR 2021
Collection time ( <i>00:00-23:59</i> )	10:15 (24 HR)
Collection date and time (derived)	9 APR 2021 10:15

US3622160

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3622160**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

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*

**US3622160**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3622160**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:29**

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"/>

**US3622160**

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

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

**Generated On: 10 Jun 2021 09:13:29**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3622160

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

Visit date (dd MMM yyyy)	2 FEB 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3622160

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:13:11

Generated On: 10 Jun 2021 09:13:29

Date of updated informed consent (dd MMM yyyy) 2 FEB 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) 2 FEB 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 \_\_\_\_\_

US3622160

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 FEB 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

2 FEB 2021 09:40

US3622160

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	09:05
Collection Date and Time (derived)	2 FEB 2021 09:05

US3622160

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 19:55:41

Generated On: 10 Jun 2021 09:13:29

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

AEID	USA-US085-2021-MRNA-1273-P30 1000016
Adverse event	CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒

Related ☐

Not Applicable ☐

Relationship to Study Procedure Not Related ☒

Related ☐

Not Applicable ☐

Action taken with investigational product None ☐

Dose Delayed ☐

Investigational Product ☐

Withdrawn ☐

Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐

Not Recovered/Not Resolved ☒

Recovered/Resolved ☐

Recovered/Resolved with ☐

Sequelae

Recovering/Resolving ☐

Unknown ☐

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

Narrative

PARTICIPANT WAS  
CONTACTED ON 06APR2021  
AND INFORMED SITE THAT  
PARTICIPANT HAD ONSET OF  
CHEST AND BACK PAIN, WHICH  
STARTED ON 04APR2021.  
PARTICIPANT STATED THEY  
WENT TO MERCY HOSPITAL ON  
05APR2021 AND WAS  
ADMITTED.

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**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

AEID	USA-US085-2021-MRNA-1273-P30 1000016
Adverse event	BACK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒

Related ☐

Not Applicable ☐

Relationship to Study Procedure Not Related ☒

Related ☐

Not Applicable ☐

Action taken with investigational product None ☐

Dose Delayed ☐

Investigational Product ☐

Withdrawn ☐

Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐

Not Recovered/Not Resolved ☒

Recovered/Resolved ☐

Recovered/Resolved with ☐

Sequelae

Recovering/Resolving ☐

Unknown ☐

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

Narrative

PARTICIPANT WAS  
CONTACTED ON 06APR2021  
AND INFORMED SITE THAT  
PARTICIPANT HAD ONSET OF  
CHEST AND BACK PAIN, WHICH  
STARTED ON 04APR2021.  
PARTICIPANT STATED THEY  
WENT TO MERCY HOSPITAL ON  
05APR2021 AND WAS  
ADMITTED.

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**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Sep 2020 13:02:27

Generated On: 10 Jun 2021 09:13:29

---

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

Yes ☒

No ☐

---

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

---

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE CORONARY SYNDROME

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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 (2)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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 (3)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication SYMTUZA

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 1987
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"/>

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication BACK PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication TOPROL XL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication ANGINA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication JANUVIA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication PERIPHERAL BILATERAL  
LOWER EXTREMITY  
NEUROPATHY

Dose per administration 600

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) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 2009
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input 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) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication ACUTE CORONARY SYNDROME

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication VENTOLIN INHALER

Prophylaxis Yes ☐  
No ☒

Indication COPD/ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication PRO AIR INHALER  
(ALBUTEROL)

Prophylaxis Yes ☐  
No ☒

Indication COPD/ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication DILTIAZEM

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication ATROVENT INHALER

Prophylaxis Yes ☐  
No ☒

Indication COPD/ASTHMA

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication SIGULAIR

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

	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 (18)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

Name of Medication CRESTOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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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EAB) (1725)

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Feb 2021 14:04:50

Generated On: 10 Jun 2021 09:13:29

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



US3622160

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:13:29

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3622160

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:29

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 ☐

US3622160

Folder: SAE USA-US085-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

SAEID	USA-US085-2021-MRNA-1273-P301000016
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3622160

Folder: SAE USA-US085-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 19:55:42

Generated On: 10 Jun 2021 09:13:29

SAEID	USA-US085-2021-MRNA-1273-P301000016
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	07/APR/2021 09:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3622160 (Prod: University of Miami)

**US3622160**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:13:29**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:04:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'US3622160'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:20:45

US3622160

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:46:38
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 03:53:33
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:31:19
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:06:35
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:10

**US3622160**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:46:38
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '05 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:20:46



**US3622160**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:46:38
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:10

**US3622160**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'SCRN'	System	05 Sep 2020 17:19:10

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:20:47

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '51'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'YEARS'	System	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '51'	System	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24



**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24



**US3622160**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:29**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:24:24

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Sep 2020'	System	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2020'	System	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47



**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:47

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:20:46

**US3622160**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:29**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'I'	System	05 Sep 2020 17:19:56

**US3622160**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:47:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:19:56

**US3622160**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:13:29**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:48:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:48:59

US3622160

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 11:51:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:51:48
Data point term sent to Coder	System	19 Sep 2020 11:50:33
User entered 'HIV infection'	(b) (4), (b) (6)	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 1987'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:49:46



**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:49:59
Signature has been broken.	(b) (4), (b) (6)	26 Oct 2020 13:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 1987'	System	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '1987'	System	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:49:46

**US3622160**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:49:46

US3622160

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:52:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:52:48
Data point term sent to Coder	System	19 Sep 2020 11:52:33
User entered 'Myocardial infarction'	(b) (4), (b) (6)	19 Sep 2020 11:51:41



**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:51:41

**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:51:41



**US3622160**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:51:41

US3622160

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:52:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:52:48
Data point term sent to Coder	System	19 Sep 2020 11:52:33
User entered 'Coronary artery disease'	(b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:52:14



**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:52:14

**US3622160**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:52:14

US3622160

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:55:41
Data point term sent to Coder	System	19 Sep 2020 11:54:34
User entered 'Hypertension'	(b) (4), (b) (6)	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:06



**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2000'	System	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2000'	System	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:54:06

**US3622160**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:54:06

US3622160

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:56:41
Data point term sent to Coder	System	19 Sep 2020 11:55:35
User entered 'Diabetes'	(b) (4), (b) (6)	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:37



**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:54:37

**US3622160**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:54:37

US3622160

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 11:57:41
Data point term sent to Coder	(b) (4)	
User entered 'Emphysema'	System	19 Sep 2020 11:56:36
	(b) (4), (b) (6)	19 Sep 2020 11:56:03



**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2017'	System	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2017'	System	19 Sep 2020 11:56:03

**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:56:03



**US3622160**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:56:03

US3622160

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:57:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:57:41
Data point term sent to Coder	System	19 Sep 2020 11:56:36
User entered 'Chronic bronchitis'	(b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2007'	System	19 Sep 2020 11:56:27



**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2007'	System	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:56:27

**US3622160**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:56:27

US3622160

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:10:54
Query 'Per DM CLR: Please note that there is no Con Junlin Long Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'please refer to conmed line 12, 13 and 15.' (Site from DM).	(b) (4) (b) (4)	29 Oct 2020 15:37:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:22:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:58:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:58:42
Data point term sent to Coder	System	19 Sep 2020 11:57:36
User entered 'Asthma (moderate)'	(b) (4), (b) (6)	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:09



**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2018'	System	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2018'	System	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:57:09

**US3622160**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:57:09

US3622160

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:58:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:58:41
Data point term sent to Coder	System	19 Sep 2020 11:57:36
User entered 'GERD'	(b) (4), (b) (6)	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:34



**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2009'	System	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2009'	System	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:57:34

**US3622160**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:57:34

US3622160

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 11:59:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:59:42
Data point term sent to Coder	System	19 Sep 2020 11:58:37
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	19 Sep 2020 11:58:00



**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2011'	System	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2011'	System	19 Sep 2020 11:58:00

**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:58:00



**US3622160**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:58:00

US3622160

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:00:42
Data point term sent to Coder	System	19 Sep 2020 11:59:37
User entered 'Acute coronary syndrome'	(b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:59:30



**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:59:30

**US3622160**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:59:30

US3622160

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 12:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:01:42
Data point term sent to Coder	System	19 Sep 2020 12:00:37
User entered 'Angina'	(b) (4), (b) (6)	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:51



**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:59:51

**US3622160**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 11:59:51

US3622160

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:15:58
Query 'Per DM CLR: Please note that there is no Con Junlin Long Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'patient had surgery in September, 2020 and does not need medication for this condition.' (Site from DM).	(b) (4) (b) (4)	29 Oct 2020 15:48:22
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:24:06
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 12:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:01:42
Data point term sent to Coder	System	19 Sep 2020 12:00:37
User entered 'Glaucoma'	(b) (4), (b) (6)	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:22



**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2020'	System	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2020'	System	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:00:22

**US3622160**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:00:22

US3622160

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:16:12
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:27:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:27:03
Data point term sent to Coder	System	29 Oct 2020 15:49:47
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:49:26
' answered with 'condition updated' (Site from DM).		
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:49:18
Coding entries removed.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:49:18
Signature has been broken.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:49:18
User entered 'peripheral NEUROPATHY' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:49:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59



US3622160

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:24:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:02:43
Data point term sent to Coder	System	19 Sep 2020 12:01:38
User entered 'Neuropathy'	(b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2009'	System	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2009'	System	19 Sep 2020 12:00:40



**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:00:40

**US3622160**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:00:40

US3622160

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 12:02:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:02:42
Data point term sent to Coder	System	19 Sep 2020 12:01:38
User entered 'Gallstones'	(b) (4), (b) (6)	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:19



**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2010'	System	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2010'	System	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2011'	System	19 Sep 2020 12:01:19

**US3622160**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2011'	System	19 Sep 2020 12:01:19

US3622160

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:03:42
Data point term sent to Coder	System	19 Sep 2020 12:02:40
User entered 'Back pain'	(b) (4), (b) (6)	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:51



**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2001'	System	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2001'	System	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:01:51

**US3622160**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:01:51

US3622160

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:28:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:53
Data point term sent to Coder	System	29 Oct 2020 15:47:43
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' answered with 'condition updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:46:53
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:46:45
Coding entries removed.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:46:45
Signature has been broken.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:46:45
User entered 'CHRONIC ARTHRITIS (Rheumatoid)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:46:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59

US3622160

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:13:29

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:25:30
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Chronic arthritis - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 12:03:42
Data point term sent to Coder	(b) (4)	
User entered 'Chronic arthritis'	Coder Import (b) (4)	19 Sep 2020 12:03:42
	(b) (4)	
	System	19 Sep 2020 12:02:38
	(b) (4), (b) (6)	19 Sep 2020 12:02:23



**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:49:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2009'	System	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2009'	System	19 Sep 2020 12:02:23

**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:02:23



**US3622160**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	19 Sep 2020 12:02:23

US3622160

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:13:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:13:24
Data point term sent to Coder	(b) (4)	
User entered 'post menopause'	System	23 Nov 2020 17:29:09
	Junlin Long (b) (4)	23 Nov 2020 17:28:41
	(b) (4)	

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'un UNK 2017'	Junlin Long (b) (4)	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '0'	Junlin Long (b) (4)	23 Nov 2020 17:28:41

US3622160

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:13:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User closed query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:27:05
Query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:19:28
User entered 'Yes (Y)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:19:22
User opened query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 02:09:11
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered empty.	Junlin Long (b) (4)	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:24:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4)	02 Feb 2021 16:19:22
User entered '1'	Junlin Long (b) (4)	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'Jan 2017'	System	23 Nov 2020 17:28:41



**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '2017'	System	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered empty.	System	23 Nov 2020 17:28:41

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '11:15'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '5 Sep 2020 11:15'	System	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '55' in	(b) (4), (b) (6)	19 Sep 2020 12:12:47
DataPoint set to visible.	System	05 Sep 2020 17:19:56



**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '156' lb	(b) (4), (b) (6)	19 Sep 2020 12:12:47
DataPoint set to visible.	System	05 Sep 2020 17:19:56

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered '36.33366'	System	19 Sep 2020 12:12:47
DataPoint set to visible.	System	05 Sep 2020 17:19:56

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'kg/m2'	System	19 Sep 2020 12:12:47
DataPoint set to visible.	System	05 Sep 2020 17:19:56

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'bpm'	System	19 Sep 2020 12:12:47



US3622160

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'breaths/min'	System	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'mmHg'	System	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:37
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User entered 'mmHg'	System	19 Sep 2020 12:12:47

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41

**US3622160**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41



**US3622160**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:13:05

**US3622160**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:51:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 12:13:05

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

US3622160

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:29

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:02:26
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'recorded in mh' (Site from DM).	Junlin Long (b) (4)	23 Nov 2020 17:28:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 05:16:56
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4)	
	(b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04



**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:29**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:14:04

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

[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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00



US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

[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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Disabled, socially active'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00



**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

**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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

[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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

US3622160

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:29

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)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:52:39
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:15:00

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:15



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:15

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:15

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'VISIT1'	System	05 Sep 2020 17:20:15

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

[What was the date of randomization? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '05 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:25:30

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '145570'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:25:30

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:25:30

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:16:00

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:16:00



US3622160

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:29

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Sep 2020 12:16:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Sep 2020 12:16:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Sep 2020 12:16:14
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Sep 2020 12:16:00
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 12:16:00

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:16:00

US3622160

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Sep 2020 12:16:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Sep 2020 12:16:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Sep 2020 12:16:14
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Sep 2020 12:16:00
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 12:16:00

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:29**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:16:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:32:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:32:50

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '11:15'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '5 Sep 2020 11:15'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'bpm'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

US3622160

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'breaths/min'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '122'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'mmHg'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'mmHg'	System	19 Sep 2020 12:18:13



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '13:29'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '5 Sep 2020 13:29'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '70'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'bpm'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'breaths/min'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '124'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'mmHg'	System	19 Sep 2020 12:18:13



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:53:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '71'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'mmHg'	System	19 Sep 2020 12:18:13

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:33

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:33

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

US3622160

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 17:20:46



US3622160

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered '12:54'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '5 Sep 2020 12:54'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:35:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:18
User entered 'ONCE'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 17:20:46

US3622160

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:33
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:54

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:33
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:54



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:33
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '11:30'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:18:54

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '5 Sep 2020 11:30'	System	19 Sep 2020 12:18:54

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '11:35'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '5 Sep 2020 11:35'	System	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Sep 2020 12:19:16



**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered empty.	System	19 Sep 2020 12:19:16

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:55:07
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:19:23

**US3622160**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered '1'	System	19 Sep 2020 12:19:23

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:28:42', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8743fda6-6d42-47c2-8b91-851b523949a8'	System	05 Sep 2020 17:29:19
User entered 'Yes (Y)'	System	05 Sep 2020 17:29:19

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:28:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8743fda6-6d42-47c2-8b91-851b523949a8' User entered '98.7'	System	05 Sep 2020 17:29:19
	System	05 Sep 2020 17:29:19



US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8743fda6-6d42-47c2-8b91-851b523949a8'	System	05 Sep 2020 17:29:19
User entered 'No (N)'	System	05 Sep 2020 17:29:19

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:17', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8743fda6-6d42-47c2-8b91-851b523949a8'	System	05 Sep 2020 17:29:19
User entered '05 Sep 2020 13:29'	System	05 Sep 2020 17:29:19

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 13:14'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 15:44'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:48:45', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91219df4-c77d-49e5-a86e-6b0b9df13d48'	System	06 Sep 2020 01:52:29
User entered 'Yes (Y)'	System	06 Sep 2020 01:52:29

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91219df4-c77d-49e5-a86e-6b0b9df13d48'	System	06 Sep 2020 01:52:29
User entered '98.1'	System	06 Sep 2020 01:52:29

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91219df4-c77d-49e5-a86e-6b0b9df13d48'	System	06 Sep 2020 01:52:29
User entered 'No (N)'	System	06 Sep 2020 01:52:29



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91219df4-c77d-49e5-a86e-6b0b9df13d48'	System	06 Sep 2020 01:52:29
User entered '05 Sep 2020 21:52'	System	06 Sep 2020 01:52:29

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 16:39'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 2'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2a30eae-e587-4697-b9d3-9b94173183e9' User entered 'No (N)'	System	06 Sep 2020 16:19:17
	System	06 Sep 2020 16:19:17

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2a30eae-e587-4697-b9d3-9b94173183e9'	System	06 Sep 2020 16:19:17
User entered 'No (N)'	System	06 Sep 2020 16:19:17

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:13', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2a30eae-e587-4697-b9d3-9b94173183e9'	System	06 Sep 2020 16:19:17
User entered '06 Sep 2020 12:19'	System	06 Sep 2020 16:19:17

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 3'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '840dd7f8-9c34-44e2-99fa-799279e1efe7'	System	07 Sep 2020 16:17:24
User entered 'No (N)'	System	07 Sep 2020 16:17:24

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:16', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '840dd7f8-9c34-44e2-99fa-799279e1efe7'	System	07 Sep 2020 16:17:24
User entered 'No (N)'	System	07 Sep 2020 16:17:24

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:22', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '840dd7f8-9c34-44e2-99fa-799279e1efe7'	System	07 Sep 2020 16:17:24
User entered '07 Sep 2020 12:17'	System	07 Sep 2020 16:17:24

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 4'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:14', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ba853b1-637a-4a8f-8cdf-b7a3e5151635'	System	08 Sep 2020 23:46:25
User entered 'No (N)'	System	08 Sep 2020 23:46:25

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:16', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ba853b1-637a-4a8f-8cdf-b7a3e5151635'	System	08 Sep 2020 23:46:25
User entered 'No (N)'	System	08 Sep 2020 23:46:25

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:22', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ba853b1-637a-4a8f-8cdf-b7a3e5151635'	System	08 Sep 2020 23:46:25
User entered '08 Sep 2020 19:46'	System	08 Sep 2020 23:46:25

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 5'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f0981bcb-e7c7-4130-a4fe-6434fdf78735'	System	09 Sep 2020 23:19:17
User entered 'No (N)'	System	09 Sep 2020 23:19:17

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f0981bcb-e7c7-4130-a4fe-6434fdf78735'	System	09 Sep 2020 23:19:17
User entered 'No (N)'	System	09 Sep 2020 23:19:17



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f0981bcb-e7c7-4130-a4fe-6434fdf78735'	System	09 Sep 2020 23:19:17
User entered '09 Sep 2020 19:19'	System	09 Sep 2020 23:19:17

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 6'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:20:44', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6a4e3296-a2c7-4906-8e5f-d3dea9004b9c'	System	10 Sep 2020 22:20:54
User entered 'No (N)'	System	10 Sep 2020 22:20:54

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:20:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6a4e3296-a2c7-4906-8e5f-d3dea9004b9c'	System	10 Sep 2020 22:20:54
User entered 'No (N)'	System	10 Sep 2020 22:20:54

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:20:51', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6a4e3296-a2c7-4906-8e5f-d3dea9004b9c'	System	10 Sep 2020 22:20:54
User entered '10 Sep 2020 18:20'	System	10 Sep 2020 22:20:54

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 7'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8df22102-16bd-4095-bd1a-17f5e99f80de'	System	11 Sep 2020 21:49:11
User entered 'No (N)'	System	11 Sep 2020 21:49:11

US3622160

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8df22102-16bd-4095-bd1a-17f5e99f80de'	System	11 Sep 2020 21:49:11
User entered 'No (N)'	System	11 Sep 2020 21:49:11

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:08', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8df22102-16bd-4095-bd1a-17f5e99f80de'	System	11 Sep 2020 21:49:11
User entered '11 Sep 2020 17:49'	System	11 Sep 2020 21:49:11

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:27', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91002a01-fcb0-42bd-856f-0e6bbaa7508b'	System	05 Sep 2020 17:29:50
User entered 'None (1)'	System	05 Sep 2020 17:29:50

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:32', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91002a01-fcb0-42bd-856f-0e6bbaa7508b'	System	05 Sep 2020 17:29:50
User entered 'No (N)'	System	05 Sep 2020 17:29:50

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:37', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91002a01-fcb0-42bd-856f-0e6bbaa7508b'	System	05 Sep 2020 17:29:50
User entered 'No (N)'	System	05 Sep 2020 17:29:50

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:42', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91002a01-fcb0-42bd-856f-0e6bbaa7508b'	System	05 Sep 2020 17:29:50
User entered 'None (1)'	System	05 Sep 2020 17:29:50

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '91002a01-fcb0-42bd-856f-0e6bbaa7508b'	System	05 Sep 2020 17:29:50
User entered '05 Sep 2020 13:29'	System	05 Sep 2020 17:29:50

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 13:14'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 15:44'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '427bc46f-8549-4fcc-a54f-5499732b3bab'	System	06 Sep 2020 01:53:48
User entered 'None (1)'	System	06 Sep 2020 01:53:48

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:26', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '427bc46f-8549-4fcc-a54f-5499732b3bab'	System	06 Sep 2020 01:53:48
User entered 'No (N)'	System	06 Sep 2020 01:53:48

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '427bc46f-8549-4fcc-a54f-5499732b3bab'	System	06 Sep 2020 01:53:48
User entered 'No (N)'	System	06 Sep 2020 01:53:48

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:36', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '427bc46f-8549-4fcc-a54f-5499732b3bab'	System	06 Sep 2020 01:53:48
User entered 'None (1)'	System	06 Sep 2020 01:53:48

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:43', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '427bc46f-8549-4fcc-a54f-5499732b3bab'	System	06 Sep 2020 01:53:48
User entered '05 Sep 2020 21:53'	System	06 Sep 2020 01:53:48

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 16:39'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 2'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'abbcd6c-3dc8-4b82-9ec1-16ac114c5f89'	System	06 Sep 2020 16:20:11
User entered 'None (1)'	System	06 Sep 2020 16:20:11

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'abbcd6c-3dc8-4b82-9ec1-16ac114c5f89'	System	06 Sep 2020 16:20:11
User entered 'No (N)'	System	06 Sep 2020 16:20:11

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:20:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'abbcd6c-3dc8-4b82-9ec1-16ac114c5f89'	System	06 Sep 2020 16:20:11
User entered 'No (N)'	System	06 Sep 2020 16:20:11

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:20:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'abbcd6c-3dc8-4b82-9ec1-16ac114c5f89'	System	06 Sep 2020 16:20:11
User entered 'None (1)'	System	06 Sep 2020 16:20:11

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:20:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'abbcd6c-3dc8-4b82-9ec1-16ac114c5f89'	System	06 Sep 2020 16:20:11
User entered '06 Sep 2020 12:20'	System	06 Sep 2020 16:20:11

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 3'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:27', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9de93876-b825-4b2c-b041-5748c304b440'	System	07 Sep 2020 16:17:44
User entered 'None (1)'	System	07 Sep 2020 16:17:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:32', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9de93876-b825-4b2c-b041-5748c304b440'	System	07 Sep 2020 16:17:44
User entered 'No (N)'	System	07 Sep 2020 16:17:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:35', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9de93876-b825-4b2c-b041-5748c304b440'	System	07 Sep 2020 16:17:44
User entered 'No (N)'	System	07 Sep 2020 16:17:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:37', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9de93876-b825-4b2c-b041-5748c304b440'	System	07 Sep 2020 16:17:44
User entered 'None (1)'	System	07 Sep 2020 16:17:44

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:41', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9de93876-b825-4b2c-b041-5748c304b440'	System	07 Sep 2020 16:17:44
User entered '07 Sep 2020 12:17'	System	07 Sep 2020 16:17:44

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 4'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:19', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '05b6ecd8-f42f-4177-b1c6-84d080f45f3e'	System	08 Sep 2020 23:47:34
User entered 'None (1)'	System	08 Sep 2020 23:47:34

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '05b6ecd8-f42f-4177-b1c6-84d080f45f3e'	System	08 Sep 2020 23:47:34
User entered 'No (N)'	System	08 Sep 2020 23:47:34

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:23', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '05b6ecd8-f42f-4177-b1c6-84d080f45f3e'	System	08 Sep 2020 23:47:34
User entered 'No (N)'	System	08 Sep 2020 23:47:34

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '05b6ecd8-f42f-4177-b1c6-84d080f45f3e'	System	08 Sep 2020 23:47:34
User entered 'None (1)'	System	08 Sep 2020 23:47:34

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:29', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '05b6ecd8-f42f-4177-b1c6-84d080f45f3e'	System	08 Sep 2020 23:47:34
User entered '08 Sep 2020 19:47'	System	08 Sep 2020 23:47:34

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 5'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:17', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '59273c98-0d36-410b-a67b-a43ba0073370'	System	09 Sep 2020 23:19:44
User entered 'None (1)'	System	09 Sep 2020 23:19:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:20', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '59273c98-0d36-410b-a67b-a43ba0073370'	System	09 Sep 2020 23:19:44
User entered 'No (N)'	System	09 Sep 2020 23:19:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '59273c98-0d36-410b-a67b-a43ba0073370'	System	09 Sep 2020 23:19:44
User entered 'No (N)'	System	09 Sep 2020 23:19:44

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:34', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '59273c98-0d36-410b-a67b-a43ba0073370'	System	09 Sep 2020 23:19:44
User entered 'None (1)'	System	09 Sep 2020 23:19:44

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '59273c98-0d36-410b-a67b-a43ba0073370'	System	09 Sep 2020 23:19:44
User entered '09 Sep 2020 19:19'	System	09 Sep 2020 23:19:44

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 6'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:20:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '4b5a0166-12ef-4593-8136-7c6c2bc71b5c'	System	10 Sep 2020 22:21:12
User entered 'None (1)'	System	10 Sep 2020 22:21:12

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:20:58', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '4b5a0166-12ef-4593-8136-7c6c2bc71b5c'	System	10 Sep 2020 22:21:12
User entered 'No (N)'	System	10 Sep 2020 22:21:12

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '4b5a0166-12ef-4593-8136-7c6c2bc71b5c'	System	10 Sep 2020 22:21:12
User entered 'No (N)'	System	10 Sep 2020 22:21:12

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '4b5a0166-12ef-4593-8136-7c6c2bc71b5c'	System	10 Sep 2020 22:21:12
User entered 'None (1)'	System	10 Sep 2020 22:21:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '4b5a0166-12ef-4593-8136-7c6c2bc71b5c'	System	10 Sep 2020 22:21:12
User entered '10 Sep 2020 18:21'	System	10 Sep 2020 22:21:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 7'	System	05 Sep 2020 17:20:46



US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:19', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2d3b93ac-17a8-489b-845c-ae7d3d1830cf'	System	11 Sep 2020 21:49:55
User entered 'None (1)'	System	11 Sep 2020 21:49:55

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2d3b93ac-17a8-489b-845c-ae7d3d1830cf'	System	11 Sep 2020 21:49:55
User entered 'No (N)'	System	11 Sep 2020 21:49:55

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:27', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2d3b93ac-17a8-489b-845c-ae7d3d1830cf'	System	11 Sep 2020 21:49:55
User entered 'No (N)'	System	11 Sep 2020 21:49:55

US3622160

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2d3b93ac-17a8-489b-845c-ae7d3d1830cf'	System	11 Sep 2020 21:49:55
User entered 'None (1)'	System	11 Sep 2020 21:49:55

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:49:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2d3b93ac-17a8-489b-845c-ae7d3d1830cf'	System	11 Sep 2020 21:49:55
User entered '11 Sep 2020 17:49'	System	11 Sep 2020 21:49:55

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:29:55', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:06', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:14', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:18', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'None (0)'	System	05 Sep 2020 17:30:32

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:23', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered 'No (N)'	System	05 Sep 2020 17:30:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T13:30:29', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '19d558da-3f3c-4de2-98f3-f2599a5259a8'	System	05 Sep 2020 17:30:32
User entered '05 Sep 2020 13:30'	System	05 Sep 2020 17:30:32



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 13:14'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 15:44'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:45', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:53', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:52:59', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'None (0)'	System	06 Sep 2020 01:53:12

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered 'No (N)'	System	06 Sep 2020 01:53:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-05T21:53:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5f1a26de-2131-4172-bc84-566aae93c484'	System	06 Sep 2020 01:53:12
User entered '05 Sep 2020 21:53'	System	06 Sep 2020 01:53:12

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Sep 2020 16:39'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 2'	System	05 Sep 2020 17:20:46

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:23', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43



US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:26', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:33', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'None (0)'	System	06 Sep 2020 16:19:43

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:35', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered 'No (N)'	System	06 Sep 2020 16:19:43

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-06T12:19:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f7fe342a-25c1-4fde-9a4c-1c012c4b4363'	System	06 Sep 2020 16:19:43
User entered '06 Sep 2020 12:19'	System	06 Sep 2020 16:19:43

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 3'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'None (0)'	System	07 Sep 2020 16:18:30

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:17:58', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'None (0)'	System	07 Sep 2020 16:18:30

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'None (0)'	System	07 Sep 2020 16:18:30

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884' User entered 'None (0)'	System	07 Sep 2020 16:18:30
	System	07 Sep 2020 16:18:30

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:14', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'None (0)'	System	07 Sep 2020 16:18:30

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:16', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'None (0)'	System	07 Sep 2020 16:18:30

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:19', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered 'No (N)'	System	07 Sep 2020 16:18:30



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-07T12:18:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '66950af2-4fdf-4bfc-bb7c-c1328dd7b884'	System	07 Sep 2020 16:18:30
User entered '07 Sep 2020 12:18'	System	07 Sep 2020 16:18:30

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 4'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:51', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:55', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:46:58', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'None (0)'	System	08 Sep 2020 23:47:16

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered 'No (N)'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-08T19:47:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '37b976ce-0827-42cb-8e85-741a6796e783'	System	08 Sep 2020 23:47:16
User entered '08 Sep 2020 19:47'	System	08 Sep 2020 23:47:16

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 5'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:52', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:19:59', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:20:06', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:20:08', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'None (0)'	System	09 Sep 2020 23:20:21

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:20:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered 'No (N)'	System	09 Sep 2020 23:20:21

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-09T19:20:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '350164ca-08aa-47d1-b9aa-f31986902e58'	System	09 Sep 2020 23:20:21
User entered '09 Sep 2020 19:20'	System	09 Sep 2020 23:20:21

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:20:46



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 6'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:13', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:19', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:23', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'None (0)'	System	10 Sep 2020 22:21:33



US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:26', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered 'No (N)'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-10T18:21:29', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '0ca92260-7a74-4445-8171-3e062020d9a1'	System	10 Sep 2020 22:21:33
User entered '10 Sep 2020 18:21'	System	10 Sep 2020 22:21:33

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 7'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered 'None (0)'	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered 'None (0)'	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1' User entered 'None (0)'	System	11 Sep 2020 21:50:32
	System	11 Sep 2020 21:50:32



**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1' User entered 'None (0)'	System	11 Sep 2020 21:50:32
	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered 'None (0)'	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:13', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered 'None (0)'	System	11 Sep 2020 21:50:32

US3622160

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered 'No (N)'	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7d5e77711b7cee7)', Time: '2020-09-11T17:50:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e73115d1-25ac-4421-81a6-95fdb2c474c1'	System	11 Sep 2020 21:50:32
User entered '11 Sep 2020 17:50'	System	11 Sep 2020 21:50:32

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:20:46

**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:13



**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:13

**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:13

**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:13

**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:21

**US3622160**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'I'	System	19 Sep 2020 12:20:21

**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:57:18
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:48

**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:57:18
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:48

**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:57:18
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:48



**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:57:18
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:48

**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:57:34
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:57

**US3622160**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:34:10
User entered 'I'	System	01 Oct 2020 14:28:57

**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:32
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:29:18

**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:32
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:29:18

**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:32
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:29:18

**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:32
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:29:18

**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:29:24



**US3622160**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:55
User entered 'I'	System	01 Oct 2020 14:29:24

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:00:58
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 15:59:44

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:00:58
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 15:59:44

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[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 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:00:58
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	03 Oct 2020 15:59:44

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'VISIT2'	System	03 Oct 2020 15:59:44

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	03 Oct 2020 17:10:01
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01



**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '10:26'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '3 Oct 2020 10:26'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '98.3' F	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Oral (Oral)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 17:10:01
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '78'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'bpm'	System	03 Oct 2020 17:10:01

US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01



US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'breaths/min'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '105'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '73'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01



US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:05:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -19 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 04:40:20
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -19 minutes. Please review and update or provide a clarification. Thank you' answered with 'corrected' (Site from DM).	Junlin Long (b) (4) (b) (4)	28 Dec 2020 16:13:52
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	28 Dec 2020 16:13:44
Signature has been broken.	Junlin Long (b) (4) (b) (4)	28 Dec 2020 16:13:44
User entered '12:30' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	28 Dec 2020 16:13:44
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -19 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 21:06:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:40:45
User entered '11:30'	Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '3 Oct 2020 12:30'	System	28 Dec 2020 16:13:44
User entered '3 Oct 2020 11:30'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '98' F	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Oral (Oral)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 17:10:01
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '70'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'bpm'	System	03 Oct 2020 17:10:01

US3622160

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '18'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01



**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'breaths/min'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '116'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '76'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	03 Oct 2020 17:10:01

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Oct 2020 17:10:12

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	Junlin Long (b) (4)	03 Oct 2020 17:10:12

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Oct 2020 16:00:00



**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 16:00:00
	(b) (4)	

US3622160

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 16:00:00
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'MRNA-1273 OR PLACEBO'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 16:00:00

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '11:49'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 16:00:00

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '3 Oct 2020 11:49'	System	03 Oct 2020 16:00:00

US3622160

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	03 Oct 2020 16:00:00

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:01:47
User entered 'ONCE'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:29**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'INTRAMUSCULAR'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:07
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Oct 2020 17:10:29

US3622160

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Sample is for V2/Day29. Data changed submitted to Preclarus. Per sponsor instructions, unscheduled kit was used due to sponsor kit inventory issues. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	27 Nov 2020 11:52:26
	(b) (4), (b) (6)	29 Oct 2020 14:50:15
	(b) (4), (b) (6)	28 Oct 2020 16:02:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Oct 2020 15:31:07
	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:29

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:07
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '10:45'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:29

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '3 Oct 2020 10:45'	System	03 Oct 2020 17:10:29

US3622160

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:13:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 01:27:16
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Sample is for V2/Day29. Data changed submitted to Preclarus. Per sponsor instructions, unscheduled kit was used due to sponsor kit inventory issues.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:56:53
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:47:01
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:45
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '3 Oct 2020'	Junlin Long (b) (4)	03 Oct 2020 17:10:42

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4)	03 Oct 2020 17:10:42

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:45
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:42



**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:45
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered '10:40'	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 17:10:42
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '3 Oct 2020 10:40'	System	03 Oct 2020 17:10:42

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4)	03 Oct 2020 17:10:42

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:45
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'No (N)'	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 17:10:42
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:45
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	03 Oct 2020 17:10:42
	(b) (4)	

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered empty.	System	03 Oct 2020 17:10:42

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:58
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	03 Oct 2020 17:10:46

**US3622160**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	03 Oct 2020 17:10:46



US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2bed7366-5607-4f47-94b5-2ee60ad3510d'	System	03 Oct 2020 16:27:13
User entered 'Yes (Y)'	System	03 Oct 2020 16:27:13

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:26:45', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2bed7366-5607-4f47-94b5-2ee60ad3510d' User entered '96.7'	System	03 Oct 2020 16:27:13

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:26:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2bed7366-5607-4f47-94b5-2ee60ad3510d'	System	03 Oct 2020 16:27:13
User entered 'No (N)'	System	03 Oct 2020 16:27:13

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2bed7366-5607-4f47-94b5-2ee60ad3510d'	System	03 Oct 2020 16:27:13
User entered '03 Oct 2020 12:27'	System	03 Oct 2020 16:27:13

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 12:09'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 14:39'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, after vaccination (at home)'	System	03 Oct 2020 16:00:00



US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:43:55', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6278a02d-29ac-4d56-8311-ad41774ea448'	System	04 Oct 2020 02:47:09
User entered 'Yes (Y)'	System	04 Oct 2020 02:47:09

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:46:38', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6278a02d-29ac-4d56-8311-ad41774ea448'	System	04 Oct 2020 02:47:09
User entered '97.9'	System	04 Oct 2020 02:47:09

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:46:53', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6278a02d-29ac-4d56-8311-ad41774ea448'	System	04 Oct 2020 02:47:09
User entered 'No (N)'	System	04 Oct 2020 02:47:09

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6278a02d-29ac-4d56-8311-ad41774ea448'	System	04 Oct 2020 02:47:09
User entered '03 Oct 2020 22:47'	System	04 Oct 2020 02:47:09

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 15:34'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 2'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:26', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'ceb2ebb4-077e-48d7-96f8-b937a376addb'	System	05 Oct 2020 02:17:40
User entered 'No (N)'	System	05 Oct 2020 02:17:40



US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:31', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'ceb2ebb4-077e-48d7-96f8-b937a376addb'	System	05 Oct 2020 02:17:40
User entered 'No (N)'	System	05 Oct 2020 02:17:40

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:34', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'ceb2ebb4-077e-48d7-96f8-b937a376addb'	System	05 Oct 2020 02:17:40
User entered '04 Oct 2020 22:17'	System	05 Oct 2020 02:17:40

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 3'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:39:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'df98c18c-4ce3-4fc5-a7af-5395cb5c1803'	System	06 Oct 2020 01:43:45
User entered 'Yes (Y)'	System	06 Oct 2020 01:43:45

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:43:22', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'df98c18c-4ce3-4fc5-a7af-5395cb5c1803'	System	06 Oct 2020 01:43:45
User entered '99.0'	System	06 Oct 2020 01:43:45

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:43:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'df98c18c-4ce3-4fc5-a7af-5395cb5c1803'	System	06 Oct 2020 01:43:45
User entered 'No (N)'	System	06 Oct 2020 01:43:45



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:43:41', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'df98c18c-4ce3-4fc5-a7af-5395cb5c1803'	System	06 Oct 2020 01:43:45
User entered '05 Oct 2020 21:43'	System	06 Oct 2020 01:43:45

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 4'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:14', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9b164b31-23fa-4ef7-992d-19c51ace10c5'	System	07 Oct 2020 05:23:26
User entered 'No (N)'	System	07 Oct 2020 05:23:26

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:20', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9b164b31-23fa-4ef7-992d-19c51ace10c5'	System	07 Oct 2020 05:23:26
User entered 'No (N)'	System	07 Oct 2020 05:23:26

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:22', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9b164b31-23fa-4ef7-992d-19c51ace10c5'	System	07 Oct 2020 05:23:26
User entered '07 Oct 2020 01:23'	System	07 Oct 2020 05:23:26

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 12:00'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 5'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b338f8f5-51f8-479f-ae4f-a631fded1719'	System	08 Oct 2020 12:17:15
User entered 'No (N)'	System	08 Oct 2020 12:17:15

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b338f8f5-51f8-479f-ae4f-a631fded1719'	System	08 Oct 2020 12:17:15
User entered 'No (N)'	System	08 Oct 2020 12:17:15

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b338f8f5-51f8-479f-ae4f-a631fded1719'	System	08 Oct 2020 12:17:15
User entered '08 Oct 2020 08:00'	System	08 Oct 2020 12:17:15

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 6'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:38', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6905d457-b540-4205-a000-9e7de83cc9e3'	System	08 Oct 2020 23:00:47
User entered 'No (N)'	System	08 Oct 2020 23:00:47

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6905d457-b540-4205-a000-9e7de83cc9e3'	System	08 Oct 2020 23:00:47
User entered 'No (N)'	System	08 Oct 2020 23:00:47

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:43', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '6905d457-b540-4205-a000-9e7de83cc9e3'	System	08 Oct 2020 23:00:47
User entered '08 Oct 2020 19:00'	System	08 Oct 2020 23:00:47

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 7'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39



US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:33', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c78a61d6-2aa6-40ea-a449-171b76f4a89c'	System	03 Oct 2020 16:27:59
User entered 'None (1)'	System	03 Oct 2020 16:27:59



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:39', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c78a61d6-2aa6-40ea-a449-171b76f4a89c'	System	03 Oct 2020 16:27:59
User entered 'No (N)'	System	03 Oct 2020 16:27:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:42', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c78a61d6-2aa6-40ea-a449-171b76f4a89c'	System	03 Oct 2020 16:27:59
User entered 'No (N)'	System	03 Oct 2020 16:27:59

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c78a61d6-2aa6-40ea-a449-171b76f4a89c'	System	03 Oct 2020 16:27:59
User entered 'None (1)'	System	03 Oct 2020 16:27:59

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c78a61d6-2aa6-40ea-a449-171b76f4a89c'	System	03 Oct 2020 16:27:59
User entered '03 Oct 2020 12:27'	System	03 Oct 2020 16:27:59

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 12:09'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 14:39'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, after vaccination (at home)'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:09', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '065fe89f-1f44-4f92-a7be-59e18938ce15'	System	04 Oct 2020 02:47:30
User entered 'None (1)'	System	04 Oct 2020 02:47:30



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:14', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '065fe89f-1f44-4f92-a7be-59e18938ce15'	System	04 Oct 2020 02:47:30
User entered 'No (N)'	System	04 Oct 2020 02:47:30

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:18', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '065fe89f-1f44-4f92-a7be-59e18938ce15'	System	04 Oct 2020 02:47:30
User entered 'No (N)'	System	04 Oct 2020 02:47:30

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:20', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '065fe89f-1f44-4f92-a7be-59e18938ce15'	System	04 Oct 2020 02:47:30
User entered 'None (1)'	System	04 Oct 2020 02:47:30

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:24', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '065fe89f-1f44-4f92-a7be-59e18938ce15'	System	04 Oct 2020 02:47:30
User entered '03 Oct 2020 22:47'	System	04 Oct 2020 02:47:30

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 15:34'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 2'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:39', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1dc48089-5c21-4c78-b8eb-defc6ffd2806'	System	05 Oct 2020 02:17:58
User entered 'None (1)'	System	05 Oct 2020 02:17:58



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:44', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1dc48089-5c21-4c78-b8eb-defc6ffd2806'	System	05 Oct 2020 02:17:58
User entered 'No (N)'	System	05 Oct 2020 02:17:58

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:47', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1dc48089-5c21-4c78-b8eb-defc6ffd2806'	System	05 Oct 2020 02:17:58
User entered 'No (N)'	System	05 Oct 2020 02:17:58

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1dc48089-5c21-4c78-b8eb-defc6ffd2806'	System	05 Oct 2020 02:17:58
User entered 'None (1)'	System	05 Oct 2020 02:17:58

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:53', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1dc48089-5c21-4c78-b8eb-defc6ffd2806'	System	05 Oct 2020 02:17:58
User entered '04 Oct 2020 22:17'	System	05 Oct 2020 02:17:58

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 3'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '3bf278b1-8c01-4fb8-98f0-9b98fe26d767'	System	06 Oct 2020 01:44:44
User entered 'None (1)'	System	06 Oct 2020 01:44:44



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:24', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '3bf278b1-8c01-4fb8-98f0-9b98fe26d767'	System	06 Oct 2020 01:44:44
User entered 'No (N)'	System	06 Oct 2020 01:44:44

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:27', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '3bf278b1-8c01-4fb8-98f0-9b98fe26d767'	System	06 Oct 2020 01:44:44
User entered 'No (N)'	System	06 Oct 2020 01:44:44

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '3bf278b1-8c01-4fb8-98f0-9b98fe26d767'	System	06 Oct 2020 01:44:44
User entered 'None (1)'	System	06 Oct 2020 01:44:44

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:35', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '3bf278b1-8c01-4fb8-98f0-9b98fe26d767'	System	06 Oct 2020 01:44:44
User entered '05 Oct 2020 21:44'	System	06 Oct 2020 01:44:44

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 4'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9a135afd-b15f-40a6-a5b9-27c93c0ae161'	System	07 Oct 2020 05:23:41
User entered 'None (1)'	System	07 Oct 2020 05:23:41



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:31', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9a135afd-b15f-40a6-a5b9-27c93c0ae161'	System	07 Oct 2020 05:23:41
User entered 'No (N)'	System	07 Oct 2020 05:23:41

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:34', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9a135afd-b15f-40a6-a5b9-27c93c0ae161'	System	07 Oct 2020 05:23:41
User entered 'No (N)'	System	07 Oct 2020 05:23:41

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:36', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9a135afd-b15f-40a6-a5b9-27c93c0ae161'	System	07 Oct 2020 05:23:41
User entered 'None (1)'	System	07 Oct 2020 05:23:41

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:39', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '9a135afd-b15f-40a6-a5b9-27c93c0ae161'	System	07 Oct 2020 05:23:41
User entered '07 Oct 2020 01:23'	System	07 Oct 2020 05:23:41

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 5'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '02927d34-18da-48ef-8665-14b91f7e2d31'	System	08 Oct 2020 12:17:27
User entered 'None (1)'	System	08 Oct 2020 12:17:27



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:23', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '02927d34-18da-48ef-8665-14b91f7e2d31'	System	08 Oct 2020 12:17:27
User entered 'No (N)'	System	08 Oct 2020 12:17:27

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '02927d34-18da-48ef-8665-14b91f7e2d31'	System	08 Oct 2020 12:17:27
User entered 'No (N)'	System	08 Oct 2020 12:17:27

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '02927d34-18da-48ef-8665-14b91f7e2d31'	System	08 Oct 2020 12:17:27
User entered 'None (1)'	System	08 Oct 2020 12:17:27

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '02927d34-18da-48ef-8665-14b91f7e2d31'	System	08 Oct 2020 12:17:27
User entered '08 Oct 2020 08:00'	System	08 Oct 2020 12:17:27

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 6'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'fa950397-bb04-4307-8885-6dca77e59085'	System	08 Oct 2020 23:01:00
User entered 'None (1)'	System	08 Oct 2020 23:01:00



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'fa950397-bb04-4307-8885-6dca77e59085'	System	08 Oct 2020 23:01:00
User entered 'No (N)'	System	08 Oct 2020 23:01:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:52', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'fa950397-bb04-4307-8885-6dca77e59085'	System	08 Oct 2020 23:01:00
User entered 'No (N)'	System	08 Oct 2020 23:01:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'fa950397-bb04-4307-8885-6dca77e59085'	System	08 Oct 2020 23:01:00
User entered 'None (1)'	System	08 Oct 2020 23:01:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:00:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'fa950397-bb04-4307-8885-6dca77e59085'	System	08 Oct 2020 23:01:00
User entered '08 Oct 2020 19:00'	System	08 Oct 2020 23:01:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 7'	System	03 Oct 2020 16:00:00

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39



US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Oct 2020 11:59'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:27:59', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:06', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:08', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'None (0)'	System	03 Oct 2020 16:28:21

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered 'No (N)'	System	03 Oct 2020 16:28:21



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T12:28:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '42bf9ff4-3c15-4fba-9f70-17f3eade8648'	System	03 Oct 2020 16:28:21
User entered '03 Oct 2020 12:28'	System	03 Oct 2020 16:28:21

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 12:09'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 14:39'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 1, after vaccination (at home)'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d'	System	04 Oct 2020 02:48:11
User entered 'None (0)'	System	04 Oct 2020 02:48:11

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:32', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d' User entered 'None (0)'	System	04 Oct 2020 02:48:11
	System	04 Oct 2020 02:48:11

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:35', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d' User entered 'None (0)'	System	04 Oct 2020 02:48:11
	System	04 Oct 2020 02:48:11

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:37', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d' User entered 'None (0)'	System	04 Oct 2020 02:48:11
	System	04 Oct 2020 02:48:11



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d'	System	04 Oct 2020 02:48:11
User entered 'None (0)'	System	04 Oct 2020 02:48:11

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:43', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d'	System	04 Oct 2020 02:48:11
User entered 'None (0)'	System	04 Oct 2020 02:48:11

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:47:53', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d'	System	04 Oct 2020 02:48:11
User entered 'No (N)'	System	04 Oct 2020 02:48:11

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-03T22:48:03', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b54a4021-f273-40de-bbdd-fe9f213fb56d' User entered '03 Oct 2020 22:48'	System	04 Oct 2020 02:48:11
	System	04 Oct 2020 02:48:11

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '03 Oct 2020 15:34'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 2'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:57', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:17:59', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:07', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'None (0)'	System	05 Oct 2020 02:18:17

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered 'No (N)'	System	05 Oct 2020 02:18:17

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-04T22:18:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '794188ba-e3f5-4f9c-9d43-954045fcd304'	System	05 Oct 2020 02:18:17
User entered '04 Oct 2020 22:18'	System	05 Oct 2020 02:18:17

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 3'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:44', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:47', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:44:57', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:45:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'None (0)'	System	06 Oct 2020 01:45:19



US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:45:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered 'No (N)'	System	06 Oct 2020 01:45:19

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-05T21:45:16', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '623afc45-29a7-4a50-a05b-ba06f24a5ff6'	System	06 Oct 2020 01:45:19
User entered '05 Oct 2020 21:45'	System	06 Oct 2020 01:45:19

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 4'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:43', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:48', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:52', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'None (0)'	System	07 Oct 2020 05:24:05

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:23:58', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered 'No (N)'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-07T01:24:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '1917ba89-67c2-40e4-9d25-7e65c51e6561'	System	07 Oct 2020 05:24:05
User entered '07 Oct 2020 01:24'	System	07 Oct 2020 05:24:05

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '06 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 5'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:35', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:38', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:42', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:44', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:47', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'None (0)'	System	08 Oct 2020 12:17:52

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered 'No (N)'	System	08 Oct 2020 12:17:52

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T08:00:52', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '637a6135-da62-45f5-a48c-bc44e8f92afe'	System	08 Oct 2020 12:17:52
User entered '08 Oct 2020 08:00'	System	08 Oct 2020 12:17:52



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '07 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 6'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:03', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:06', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33



**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:17', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'None (0)'	System	08 Oct 2020 23:01:33

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:22', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered 'No (N)'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-10-08T19:01:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'eb1a7ea0-b0e1-4beb-a534-9e33c68b7246'	System	08 Oct 2020 23:01:33
User entered '08 Oct 2020 19:01'	System	08 Oct 2020 23:01:33

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '08 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 11:59'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	03 Oct 2020 16:00:00
User entered 'Day 7'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39



US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

US3622160

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:29

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 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '09 Oct 2020 12:00'	System	03 Oct 2020 16:00:00

**US3622160**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
User entered '10 Oct 2020 11:59'	System	03 Oct 2020 16:00:00



**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:04:42
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:02:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:27:38

**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:04:42
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:02:27
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:27:38

**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:04:42
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:02:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:27:38

**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:04:42
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:02:27
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:27:38

**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:04
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:02:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:27:25

**US3622160**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	13 Oct 2020 18:27:25

**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:24
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:57:27
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:55:25

**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:24
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:57:27
User entered '19 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:55:25



**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:24
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:57:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:55:25

**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:24
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:57:27
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	20 Oct 2020 12:55:25
	(b) (4)	

**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:05:35
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:57:27
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:55:29

**US3622160**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	20 Oct 2020 12:55:29

**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:12
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 17:56:01

**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:12
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '26 Oct 2020'	Junlin Long (b) (4)	26 Oct 2020 17:56:01

**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:12
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	26 Oct 2020 17:56:01

**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:12
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered empty.	Junlin Long (b) (4)	26 Oct 2020 17:56:01



**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:25
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 17:56:05

**US3622160**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	26 Oct 2020 17:56:05

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Oct 2020 15:30:37

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '29 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:30:37

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[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 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:47:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	29 Oct 2020 15:30:37

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'VISIT3'	System	29 Oct 2020 15:30:37

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '29 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01



**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '10:40'	(b) (4)	
	Junlin Long (b) (4)	29 Oct 2020 15:31:01
	(b) (4)	

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '29 Oct 2020 10:40'	System	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '99.2' F	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Oral (Oral)'	Junlin Long (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '70'	Junlin Long (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'bpm'	System	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '20'	Junlin Long (b) (4)	29 Oct 2020 15:31:01



**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'breaths/min'	System	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '110'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '74'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'mmHg'	System	29 Oct 2020 15:31:01

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:36
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:04



**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:36
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Oct 2020 15:31:04
	(b) (4)	

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:48
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Oct 2020 15:31:12

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:48
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '29 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:12

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:48
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered '10:55'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:31:12

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered '29 Oct 2020 10:55'	System	29 Oct 2020 15:31:12

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:48:58
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Oct 2020 15:31:16

**US3622160**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	29 Oct 2020 15:31:16

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 64'	System	05 Sep 2020 17:20:46



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '05 Nov 2020 00:01'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '09 Nov 2020 23:59'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 71'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-13T16:46:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8bf60974-c5b7-4668-9fd1-7d1dba5d11ec'	System	13 Nov 2020 21:47:18
User entered 'No (N)'	System	13 Nov 2020 21:47:18

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Have you been exposed to someone with 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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-13T16:46:58', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8bf60974-c5b7-4668-9fd1-7d1dba5d11ec'	System	13 Nov 2020 21:47:18
User entered 'No (N)'	System	13 Nov 2020 21:47:18

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-13T16:47:02', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8bf60974-c5b7-4668-9fd1-7d1dba5d11ec'	System	13 Nov 2020 21:47:18
User entered '13 Nov 2020 16:47:02'	System	13 Nov 2020 21:47:18

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '12 Nov 2020 00:01'	System	05 Sep 2020 17:20:46



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '16 Nov 2020 23:59'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered 'Day 78'	System	05 Sep 2020 17:20:46

US3622160

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:29

[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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-19T14:27:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '83aa98d6-0909-41b7-ab35-c21cd88bb84f'	System	19 Nov 2020 19:27:39
User entered 'No (N)'	System	19 Nov 2020 19:27:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-19T14:27:20', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '83aa98d6-0909-41b7-ab35-c21cd88bb84f'	System	19 Nov 2020 19:27:39
User entered 'No (N)'	System	19 Nov 2020 19:27:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-19T14:27:25', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '83aa98d6-0909-41b7-ab35-c21cd88bb84f' User entered '19 Nov 2020 14:27:25'	System	19 Nov 2020 19:27:39
	System	19 Nov 2020 19:27:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '19 Nov 2020 00:01'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:17:39
Data entry locked.	System	05 Sep 2020 17:20:46
User entered '23 Nov 2020 23:59'	System	05 Sep 2020 17:20:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2020-11-24T12:30:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8e3fb6e8-e006-40f3-88d6-13254e9d4219'	System	24 Nov 2020 17:31:10
User entered 'No (N)'	System	24 Nov 2020 17:31:10

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2020-11-24T12:30:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8e3fb6e8-e006-40f3-88d6-13254e9d4219'	System	24 Nov 2020 17:31:10
User entered 'No (N)'	System	24 Nov 2020 17:31:10

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-24T12:30:56', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '8e3fb6e8-e006-40f3-88d6-13254e9d4219'	System	24 Nov 2020 17:31:10
User entered '24 Nov 2020 12:30:56'	System	24 Nov 2020 17:31:10

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2020-11-30T09:20:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'dbf10a78-e951-43a7-8bd0-7eae5647ec4'	System	30 Nov 2020 14:20:25
User entered 'No (N)'	System	30 Nov 2020 14:20:25

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2020-11-30T09:20:05', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'dbf10a78-e951-43a7-8bd0-7eae5647ec4'	System	30 Nov 2020 14:20:25
User entered 'No (N)'	System	30 Nov 2020 14:20:25



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-11-30T09:20:10', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'dbf10a78-e951-43a7-8bd0-7eae5647ec4'	System	30 Nov 2020 14:20:25
User entered '30 Nov 2020 09:20:10'	System	30 Nov 2020 14:20:25

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2020-12-18T16:09:50', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '385fa1d9-3430-42cf-baee-76c42f65e8f6'	System	18 Dec 2020 21:10:22
User entered 'No (N)'	System	18 Dec 2020 21:10:22



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2020-12-18T16:09:55', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '385fa1d9-3430-42cf-baee-76c42f65e8f6'	System	18 Dec 2020 21:10:22
User entered 'No (N)'	System	18 Dec 2020 21:10:22

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-12-18T16:10:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '385fa1d9-3430-42cf-baee-76c42f65e8f6'	System	18 Dec 2020 21:10:22
User entered '18 Dec 2020 16:10:01'	System	18 Dec 2020 21:10:22

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2020-12-22T15:36:42', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f219e7cd-6db5-4fea-b4bc-9d4e37ed5a1f'	System	22 Dec 2020 20:37:20
User entered 'No (N)'	System	22 Dec 2020 20:37:20

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2020-12-22T15:36:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f219e7cd-6db5-4fea-b4bc-9d4e37ed5a1f'	System	22 Dec 2020 20:37:20
User entered 'No (N)'	System	22 Dec 2020 20:37:20

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-12-22T15:36:55', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f219e7cd-6db5-4fea-b4bc-9d4e37ed5a1f'	System	22 Dec 2020 20:37:20
User entered '22 Dec 2020 15:36:55'	System	22 Dec 2020 20:37:20



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2020-12-29T11:34:18', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e0d2c4fa-704c-4b96-82db-4a2a0ae5f2b1'	System	29 Dec 2020 16:34:44
User entered 'No (N)'	System	29 Dec 2020 16:34:44

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2020-12-29T11:34:21', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e0d2c4fa-704c-4b96-82db-4a2a0ae5f2b1'	System	29 Dec 2020 16:34:44
User entered 'No (N)'	System	29 Dec 2020 16:34:44

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2020-12-29T11:34:24', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e0d2c4fa-704c-4b96-82db-4a2a0ae5f2b1'	System	29 Dec 2020 16:34:44
User entered '29 Dec 2020 11:34:24'	System	29 Dec 2020 16:34:44

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-01-05T00:33:43', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b571c031-53b4-48b8-9a9f-ee5a767b97a7'	System	05 Jan 2021 05:34:11
User entered 'No (N)'	System	05 Jan 2021 05:34:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-01-05T00:33:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b571c031-53b4-48b8-9a9f-ee5a767b97a7'	System	05 Jan 2021 05:34:11
User entered 'No (N)'	System	05 Jan 2021 05:34:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-01-05T00:33:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'b571c031-53b4-48b8-9a9f-ee5a767b97a7'	System	05 Jan 2021 05:34:11
User entered '05 Jan 2021 00:33:49'	System	05 Jan 2021 05:34:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-01-11T19:55:12', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c42342ce-37e1-4a67-9d9b-859ff081c82b'	System	12 Jan 2021 00:55:58
User entered 'No (N)'	System	12 Jan 2021 00:55:58



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-01-11T19:55:19', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c42342ce-37e1-4a67-9d9b-859ff081c82b'	System	12 Jan 2021 00:55:58
User entered 'No (N)'	System	12 Jan 2021 00:55:58

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-01-11T19:55:34', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c42342ce-37e1-4a67-9d9b-859ff081c82b'	System	12 Jan 2021 00:55:58
User entered '11 Jan 2021 19:55:34'	System	12 Jan 2021 00:55:58

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-01-18T09:44:46', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '26ab3f7d-ed11-45cc-a612-14841d6bedff'	System	18 Jan 2021 14:45:23
User entered 'No (N)'	System	18 Jan 2021 14:45:23

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-01-18T09:44:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '26ab3f7d-ed11-45cc-a612-14841d6bedff'	System	18 Jan 2021 14:45:23
User entered 'No (N)'	System	18 Jan 2021 14:45:23

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-01-18T09:44:52', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '26ab3f7d-ed11-45cc-a612-14841d6bedff'	System	18 Jan 2021 14:45:23
User entered '18 Jan 2021 09:44:52'	System	18 Jan 2021 14:45:23



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-01-25T13:22:28', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c25ea4e1-18fb-4636-bf32-32718d9e0689'	System	25 Jan 2021 18:23:02
User entered 'No (N)'	System	25 Jan 2021 18:23:02

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-01-25T13:22:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c25ea4e1-18fb-4636-bf32-32718d9e0689'	System	25 Jan 2021 18:23:02
User entered 'No (N)'	System	25 Jan 2021 18:23:02

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-01-25T13:22:34', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'c25ea4e1-18fb-4636-bf32-32718d9e0689' User entered '25 Jan 2021 13:22:34'	System	25 Jan 2021 18:23:02

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-02-01T08:28:57', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e85b01dc-abb9-4dea-b3eb-4b580435bbb5'	System	01 Feb 2021 13:29:37
User entered 'No (N)'	System	01 Feb 2021 13:29:37

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-02-01T08:29:01', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e85b01dc-abb9-4dea-b3eb-4b580435bbb5'	System	01 Feb 2021 13:29:37
User entered 'No (N)'	System	01 Feb 2021 13:29:37

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-02-01T08:29:04', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e85b01dc-abb9-4dea-b3eb-4b580435bbb5'	System	01 Feb 2021 13:29:37
User entered '01 Feb 2021 08:29:04'	System	01 Feb 2021 13:29:37

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-02-08T09:42:08', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2ea4637-0c62-41a8-bae9-430fef53c87b'	System	08 Feb 2021 14:42:50
User entered 'No (N)'	System	08 Feb 2021 14:42:50



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-02-08T09:42:11', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2ea4637-0c62-41a8-bae9-430fef53c87b'	System	08 Feb 2021 14:42:50
User entered 'No (N)'	System	08 Feb 2021 14:42:50

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-02-08T09:42:15', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e2ea4637-0c62-41a8-bae9-430fef53c87b'	System	08 Feb 2021 14:42:50
User entered '08 Feb 2021 09:42:15'	System	08 Feb 2021 14:42:50

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-02-16T21:38:49', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'd00db527-1ca6-4284-a60b-a8291b4eda83'	System	17 Feb 2021 02:40:46
User entered 'No (N)'	System	17 Feb 2021 02:40:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-02-16T21:39:03', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'd00db527-1ca6-4284-a60b-a8291b4eda83'	System	17 Feb 2021 02:40:46
User entered 'No (N)'	System	17 Feb 2021 02:40:46

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-02-16T21:39:08', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'd00db527-1ca6-4284-a60b-a8291b4eda83'	System	17 Feb 2021 02:40:46
User entered '16 Feb 2021 21:39:08'	System	17 Feb 2021 02:40:46



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-02-25T11:57:54', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '70ff47f1-b05a-4b49-983c-42d95ea4c2b6'	System	25 Feb 2021 16:58:42
User entered 'No (N)'	System	25 Feb 2021 16:58:42

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-02-25T11:57:57', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '70ff47f1-b05a-4b49-983c-42d95ea4c2b6'	System	25 Feb 2021 16:58:42
User entered 'No (N)'	System	25 Feb 2021 16:58:42

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-02-25T11:58:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '70ff47f1-b05a-4b49-983c-42d95ea4c2b6'	System	25 Feb 2021 16:58:42
User entered '25 Feb 2021 11:58:00'	System	25 Feb 2021 16:58:42

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-03-01T09:46:24', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f6839081-99a5-4ea1-9cb9-1f1f83c2a90b'	System	01 Mar 2021 14:47:11
User entered 'No (N)'	System	01 Mar 2021 14:47:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-03-01T09:46:26', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f6839081-99a5-4ea1-9cb9-1f1f83c2a90b'	System	01 Mar 2021 14:47:11
User entered 'No (N)'	System	01 Mar 2021 14:47:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-01T09:46:30', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'f6839081-99a5-4ea1-9cb9-1f1f83c2a90b'	System	01 Mar 2021 14:47:11
User entered '01 Mar 2021 09:46:30'	System	01 Mar 2021 14:47:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-03-09T07:46:13-05:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2666b67f-c81c-49c5-a4ef-7f8522bd1719'	System	09 Mar 2021 12:47:14
User entered 'No (N)'	System	09 Mar 2021 12:47:14



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-03-09T07:46:20-05:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2666b67f-c81c-49c5-a4ef-7f8522bd1719'	System	09 Mar 2021 12:47:14
User entered 'No (N)'	System	09 Mar 2021 12:47:14

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-09T07:46:28-05:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '2666b67f-c81c-49c5-a4ef-7f8522bd1719'	System	09 Mar 2021 12:47:14
User entered '09 Mar 2021 07:46:28'	System	09 Mar 2021 12:47:14

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-03-15T16:03:04-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e6a9aef1-cb35-4a58-9c15-25b709015b87'	System	15 Mar 2021 20:03:55
User entered 'No (N)'	System	15 Mar 2021 20:03:55

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-03-15T16:03:07-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e6a9aef1-cb35-4a58-9c15-25b709015b87'	System	15 Mar 2021 20:03:55
User entered 'No (N)'	System	15 Mar 2021 20:03:55

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-15T16:03:10-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e6a9aef1-cb35-4a58-9c15-25b709015b87'	System	15 Mar 2021 20:03:55
User entered '15 Mar 2021 16:03:10'	System	15 Mar 2021 20:03:55



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-03-23T16:14:54-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e4d847e8-84fa-4c22-8337-a5f3421d08bf'	System	23 Mar 2021 20:15:49
User entered 'No (N)'	System	23 Mar 2021 20:15:49

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-03-23T16:14:56-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e4d847e8-84fa-4c22-8337-a5f3421d08bf'	System	23 Mar 2021 20:15:49
User entered 'No (N)'	System	23 Mar 2021 20:15:49

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-23T16:15:01-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'e4d847e8-84fa-4c22-8337-a5f3421d08bf'	System	23 Mar 2021 20:15:49
User entered '23 Mar 2021 16:15:01'	System	23 Mar 2021 20:15:49

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (d5738a88507a1a32)', Time: '2021-03-29T18:41:35-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '599654e7-be62-4a1c-b5b8-c14e2a4a1681' User entered 'No (N)'	System	29 Mar 2021 22:43:11
	System	29 Mar 2021 22:43:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (d5738a88507a1a32)', Time: '2021-03-29T18:41:47-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '599654e7-be62-4a1c-b5b8-c14e2a4a1681'	System	29 Mar 2021 22:43:11
User entered 'No (N)'	System	29 Mar 2021 22:43:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-29T18:42:20-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '599654e7-be62-4a1c-b5b8-c14e2a4a1681' User entered '29 Mar 2021 18:42:20'	System	29 Mar 2021 22:43:11
	System	29 Mar 2021 22:43:11

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (0dd508377a28a6dc)', Time: '2021-04-09T10:36:47-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ac4125f-b5a2-4b48-b209-7da2ecb5eaba' User entered 'No (N)'	System	09 Apr 2021 14:36:58



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (0dd508377a28a6dc)', Time: '2021-04-09T10:36:50-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ac4125f-b5a2-4b48-b209-7da2ecb5eaba'	System	09 Apr 2021 14:36:58
User entered 'No (N)'	System	09 Apr 2021 14:36:58

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dd508377a28a6dc)', Time: '2021-04-09T10:36:53-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '5ac4125f-b5a2-4b48-b209-7da2ecb5eaba' User entered '09 Apr 2021 10:36:53'	System	09 Apr 2021 14:36:58
	System	09 Apr 2021 14:36:58

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (0dd508377a28a6dc)', Time: '2021-04-15T12:01:09-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'bac23292-2d5d-4959-a071-fb583502f669' User entered 'No (N)'	System	15 Apr 2021 16:02:30
	System	15 Apr 2021 16:02:30

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (0dd508377a28a6dc)', Time: '2021-04-15T12:01:11-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'bac23292-2d5d-4959-a071-fb583502f669'	System	15 Apr 2021 16:02:30
User entered 'No (N)'	System	15 Apr 2021 16:02:30

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dd508377a28a6dc)', Time: '2021-04-15T12:01:13-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: 'bac23292-2d5d-4959-a071-fb583502f669'	System	15 Apr 2021 16:02:30
User entered '15 Apr 2021 12:01:13'	System	15 Apr 2021 16:02:30



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[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 (0dd508377a28a6dc)', Time: '2021-04-20T07:47:51-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '64b2b796-64a2-430d-af48-c17a2954ef51'	System	20 Apr 2021 11:48:01
User entered 'No (N)'	System	20 Apr 2021 11:48:01

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

Have you been exposed to someone with 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 (0dd508377a28a6dc)', Time: '2021-04-20T07:47:53-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '64b2b796-64a2-430d-af48-c17a2954ef51'	System	20 Apr 2021 11:48:01
User entered 'No (N)'	System	20 Apr 2021 11:48:01

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dd508377a28a6dc)', Time: '2021-04-20T07:47:58-04:00', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '64b2b796-64a2-430d-af48-c17a2954ef51' User entered '20 Apr 2021 07:47:58'	System	20 Apr 2021 11:48:01
	System	20 Apr 2021 11:48:01

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:45:39

**US3622160**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 05:45:39



**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 05:45:39

**US3622160**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:39
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 05:45:39

US3622160

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:13:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-01T09:46:40', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '54418452-648c-4373-beca-eea13d4213b0'	System	01 Mar 2021 14:47:29
User entered 'No (N)'	System	01 Mar 2021 14:47:29

**US3622160**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:51:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d5738a88507a1a32)', Time: '2021-03-01T09:46:44', User OID: 'PatientReportedOutcome (US3622160)', ODM File OID: '54418452-648c-4373-beca-eea13d4213b0'	System	01 Mar 2021 14:47:29
User entered '01 Mar 2021 09:46:44'	System	01 Mar 2021 14:47:29

**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:29:27
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 17:35:51

**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:29:27
User entered '27 Nov 2020'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 17:35:51

**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:29:27
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 17:35:51



**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:29:27
User entered empty.	Junlin Long (b) (4) (b) (4)	30 Nov 2020 17:35:51

**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:29:18
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 17:35:58

**US3622160**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:47
User entered 'I'	System	30 Nov 2020 17:35:58

**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:56:51
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User entered 'Yes (Y)'	Junlin Long (b) (4)	30 Dec 2020 15:16:16

**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:56:51
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User entered '30 Dec 2020'	Junlin Long (b) (4)	30 Dec 2020 15:16:16

**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:56:51
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	30 Dec 2020 15:16:16

**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:56:51
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User entered empty.	Junlin Long (b) (4)	30 Dec 2020 15:16:16

**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:56:58
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
User entered 'Yes (Y)'	Junlin Long (b) (4)	30 Dec 2020 15:16:18



**US3622160**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
User entered 'I'	System	30 Dec 2020 15:16:18

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:57:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:17:58

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:57:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:17:58

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:57:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:17:58

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:57:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	02 Feb 2021 16:17:58
	(b) (4)	

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:57:43
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:18:01

**US3622160**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
User entered 'I'	System	02 Feb 2021 16:18:01

**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:57



**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:18
User entered '2 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:57

**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:57

**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:01:34
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:57

**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:01:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:00:24

**US3622160**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:27:46
User entered 'I'	System	02 Mar 2021 15:00:24

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:25:18
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Apr 2021 15:13:06

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:25:18
User entered '2 Apr 2021'	Junlin Long (b) (4) (b) (4)	02 Apr 2021 15:13:06

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:25:18
User entered 'Clinic (Clinic)'	Junlin Long (b) (4) (b) (4)	02 Apr 2021 15:13:06



**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	02 Apr 2021 15:13:06

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '2 Apr 2021'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '09:25'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 09:25'	System	02 Apr 2021 15:13:29

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '98.2' F	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered 'Oral (Oral)'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered empty.	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	



**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '78'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 15:13:29

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '20'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 15:13:29

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '148'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 15:13:29

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:35
User entered '84'	Junlin Long (b) (4)	02 Apr 2021 15:13:29
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 15:13:29



**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:46
User entered 'No (N)'	Junlin Long (b) (4)	02 Apr 2021 15:13:34
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:46
User entered empty.	Junlin Long (b) (4)	02 Apr 2021 15:13:34
	(b) (4)	

US3622160

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:54
User entered 'No (N)'	Junlin Long (b) (4)	02 Apr 2021 15:13:40
	(b) (4)	

US3622160

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 17:19:13
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'Blood could not be obtained during the participant's last visit on 02APR2021. The participant came in today (e.g., 09APR2021) and their blood was drawn.' (Site from System).	(b) (4)	
	Junlin Long (b) (4)	09 Apr 2021 14:38:48
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Apr 2021 14:36:45
DataPoint Un-verified.	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
User entered '9 Apr 2021' reason for change: New Information	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:54
User entered empty.	Junlin Long (b) (4)	02 Apr 2021 15:13:40
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
User entered '10:15' reason for change: New Information	Junlin Long (b) (4)	09 Apr 2021 14:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:26:54
User entered empty.	Junlin Long (b) (4)	02 Apr 2021 15:13:40
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 10:15'	System	09 Apr 2021 14:36:45
User entered empty.	System	02 Apr 2021 15:13:40

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:27:02
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Apr 2021 15:13:43
	(b) (4)	

**US3622160**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 15:13:43



**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:31
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:16:53

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:31
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:16:53

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:31
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	02 Feb 2021 16:16:53

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 16:16:53

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:11
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:43:47

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:11
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:43:47



**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:58:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'No (N)'	Junlin Long (b) (4)	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User entered empty.	System	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:29**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User entered empty.	System	02 Feb 2021 16:17:12

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:17:24



**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:17:24

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '09:40'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:17:24

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User entered '2 Feb 2021 09:40'	System	02 Feb 2021 16:17:24

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:16
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 16:17:34

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:16
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '2 Feb 2021'	Junlin Long (b) (4)	02 Feb 2021 16:17:34

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:16
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User entered '09:05'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:17:34

**US3622160**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:29**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:47
User entered '2 Feb 2021 09:05'	System	02 Feb 2021 16:17:34

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:13:29**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:00
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:14:34
DataPoint Un-verified.	Junlin Long (b) (4)	06 Apr 2021 16:55:38
Signature has been broken.	(b) (4) Junlin Long (b) (4)	06 Apr 2021 16:55:38
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	06 Apr 2021 16:55:38
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	14 Jan 2021 15:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:39:09
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	14 Dec 2020 14:19:50



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:20:49
User entered 'USA-US085-2021-mRNA-1273-P301000016'	System	07 Apr 2021 13:20:33
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 13:20:33

US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:06:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:06:14
Data point term sent to Coder	System	06 Apr 2021 17:00:43
User entered 'chest pain'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '4 Apr 2021'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 16:59:41



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:00:48
	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	06 Apr 2021 17:04:49
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	06 Apr 2021 16:59:41
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	



US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 17:04:49
User entered '1' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:04:49
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '5 Apr 2021' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:04:49
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41

US3622160

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:01:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:04:49
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 16:59:41
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 16:59:41
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:00:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 16:59:41



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:02:16
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:02:06
User opened query 'PV Query: Please consider updating the event terms to the underlying cause/etiology of the event. If no underlying cause, please consider updating event terms to 'worsening of chest pain' and 'worsening of back pain' as subject has history of angina and back pain.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:01:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:01:11
User opened query 'PV Query: Please confirm if concomitant medication Ventolin inhaler and pro air inhaler are the same thing or separate medications.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:00:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Participant was contacted on 06APR2021 and informed site that participant had onset of chest and back pain, which started on 04APR2021. Participant stated they went to Mercy Hospital on 05APR2021 and was admitted.' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:04:49
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 16:59:41

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 17:04:49

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:22:47
User entered 'USA-US085-2021-mRNA-1273-P301000016'	(b) (4), (b) (6)	07 Apr 2021 13:22:40

US3622160

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:06:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:06:13
Data point term sent to Coder	System	06 Apr 2021 17:00:44
User entered 'back pain'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '4 Apr 2021'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:03:57
	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:00:18



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

US3622160

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	06 Apr 2021 17:01:10
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	06 Apr 2021 17:00:18
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

US3622160

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 17:01:10
User entered '1' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:01:10
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '5 Apr 2021' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:01:10
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:03:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:01:10
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 17:00:18
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18



**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered '0'	Junlin Long (b) (4)	06 Apr 2021 17:00:18
	(b) (4)	

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:03:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered empty.	Junlin Long (b) (4) (b) (4)	06 Apr 2021 17:00:18

US3622160

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:03:32
User opened query 'PV Query: Please consider updating the event terms to the underlying cause/etiology of the event. If no underlying cause, please consider updating event terms to 'worsening of chest pain' and 'worsening of back pain' as subject has history of angina and back pain.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:03:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:02:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:20
User entered 'Participant was contacted on 06APR2021 and informed site that participant had onset of chest and back pain, which started on 04APR2021. Participant stated they went to Mercy Hospital on 05APR2021 and was admitted.' reason for change: New Information	Junlin Long (b) (4)	06 Apr 2021 17:05:19
User entered empty.	Junlin Long (b) (4)	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:00:18

**US3622160**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 17:01:10



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:13:29**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:00
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 15:20:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:20:59

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Sep 2020 08:28:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:28:43
Data point term sent to Coder	System	19 Sep 2020 12:22:41
User entered 'Aspirin'	(b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Acute coronary syndrome'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '81'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:03



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:22:03

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:22:03

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
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) (b) (4)	19 Sep 2020 12:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:24:43
Data point term sent to Coder	System	19 Sep 2020 12:23:42
User entered 'Atorvastatin'	(b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:22:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:22:53

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:24:43
Data point term sent to Coder	System	19 Sep 2020 12:23:43
User entered 'Omeprazole'	(b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:23:35

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:23:35

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: COBICISTAT;DARUNAVIR ETHANOLATE;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: SYMTUZA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:25:44
Data point term sent to Coder	System	19 Sep 2020 12:24:44
User entered 'Symtuza'	(b) (4), (b) (6)	19 Sep 2020 12:24:31



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'HIV'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 1987'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:24:31

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:24:31



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:24:31

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
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) Coders Import (b) (4) (b) (4)	19 Sep 2020 12:26:44
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	19 Sep 2020 12:26:44
Data point term sent to Coders	System	19 Sep 2020 12:25:45
User entered 'Vitamin D3'	(b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:25:18



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:25:18

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:25:18

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:27:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:27:44
Data point term sent to Coder	System	19 Sep 2020 12:26:45
User entered 'Tramadol'	(b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Back pain'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:26:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:26:10

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL XL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:28:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:28:44
Data point term sent to Coder	System	19 Sep 2020 12:27:45
User entered 'Toprol XL'	(b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:27:01

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:27:01

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 13:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 13:00:44
Data point term sent to Coder	System	19 Sep 2020 12:59:54
Data point term sent to Coder	System	19 Sep 2020 12:29:46
User entered 'Nitroglycerin'	(b) (4), (b) (6)	19 Sep 2020 12:29:16



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Angina'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0.4'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4)	19 Sep 2020 12:59:46
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	19 Sep 2020 12:59:46
Data Entry Error		
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	19 Sep 2020 12:29:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Sep 2020 12:29:16



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Sublingual'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:29:16

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:29:16



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:29:16

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 12:31:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:31:44
Data point term sent to Coder User entered 'Januvia'	System (b) (4), (b) (6)	19 Sep 2020 12:30:46 19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Diabetes'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '100'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:08



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:30:08

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:30:08

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 21:51:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 21:51:21
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:36:58 06 Nov 2020 15:36:03
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:40:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:32:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 12:32:47
Data point term sent to Coder User entered 'Gabapentin'	System (b) (4), (b) (6) (b) (4)	19 Sep 2020 12:31:47 19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:41:17
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'indication updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:36:12
Signature has been broken.	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:36:03
User entered 'peripheral bilateral lower extremity NEUROPATHY' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:36:03
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:58:04
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Neuropathy'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '600'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 12:30:57

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 12:30:57

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Sep 2020 08:25:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:25:42
Data point term sent to Coder	System	19 Sep 2020 13:28:07
User entered 'CLOPIDOGREL' reason for change:	(b) (4), (b) (6)	19 Sep 2020 13:27:55
Data Entry Error		
Data point term sent to Coder	System	19 Sep 2020 12:33:47
User entered 'Cloidegrol'	(b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Acute coronary syndrome'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
User entered '1'	System	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
User entered '1'	System	19 Sep 2020 12:32:53

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:55:27
User entered '804 (804)'	System	19 Sep 2020 12:32:53

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:42:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:42:13
Data point term sent to Coder	System	29 Oct 2020 15:36:29
Coding entries removed.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:35:55
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:40:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:42:41
Data point term sent to Coder	System	19 Sep 2020 12:34:48
User entered 'Ventolin inhaler'	(b) (4), (b) (6) (b) (4)	19 Sep 2020 12:34:21



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
Signature has been broken.	Junlin Long	29 Oct 2020 15:35:55
User entered 'COPD/asthma' reason for change: Per Query Resolution	Junlin Long	29 Oct 2020 15:35:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'COPD'		19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Sep 2020 12:35:12
User entered 'UN UNK 2018' reason for change:	(b) (4), (b) (6)	19 Sep 2020 12:35:12
Data Entry Error		
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Sep 2020 12:34:21
User entered 'un UNK 201' (non-conformant).	(b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:34:21

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:34:21



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 12:34:21

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:56:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:56:06
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:36:31 29 Oct 2020 15:36:21
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:40:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:54:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:54:45
Data point term sent to Coder	System	28 Sep 2020 19:49:55
User closed query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	28 Sep 2020 19:49:24

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'albuterol added to term' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 19:49:24
User entered 'PRO AIR INHALER (albuterol)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 19:49:07
User opened query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	23 Sep 2020 10:10:46
Data point term sent to Coder	System	19 Sep 2020 13:01:54
User entered 'Pro Air inhaler'	(b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
Signature has been broken.	Junlin Long	29 Oct 2020 15:36:21
User entered 'COPD/asthma' reason for change: Per Query Resolution	Junlin Long	29 Oct 2020 15:36:21
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'COPD'		19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:01:10

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:01:10

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 13:03:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 13:03:48
Data point term sent to Coder User entered 'Diltiazem'	System (b) (4), (b) (6)	19 Sep 2020 13:02:55 19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '120'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:02:52

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 13:02:52

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:10:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:10:44
Data point term sent to Coder	System	29 Oct 2020 15:37:32
Coding entries removed.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:36:43
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:40:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:23:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:23:41
Data point term sent to Coder	System	19 Sep 2020 13:18:02
User entered 'Atrovent inhaler'	(b) (4), (b) (6) (b) (4)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04



US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
Signature has been broken.	Junlin Long	29 Oct 2020 15:36:43
User entered 'COPD/asthma' reason for change: Per Query Resolution	Junlin Long	29 Oct 2020 15:36:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'COPD'		19 Sep 2020 13:17:04

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 mcg/2.5 mL; 18 mcg/inh; CFC free 17 mcg/inh, etc) instead of numner of puff, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 03:05:23
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 mcg/2.5 mL; 18 mcg/inh; CFC free 17 mcg/inh, etc) instead of numner of puff, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:20:33
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:20:28
User entered '17' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:20:28
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 mcg/2.5 mL; 18 mcg/inh; CFC free 17 mcg/inh, etc) instead of numner of puff, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:53:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:04:50
Signature has been broken.	Junlin Long	02 Feb 2021 16:20:28
User entered 'ug (ug)' reason for change: Per Query Resolution	Junlin Long	02 Feb 2021 16:20:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'puff (PUFF)'		19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:17:04

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 13:17:04



US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:39:18
User coded data point as Term Coded data point by	Coder Import (b) (4)	06 Nov 2020 15:39:18
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	06 Nov 2020 15:39:01
Coding entries removed.	Junlin Long (b) (4)	06 Nov 2020 15:38:24
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 13:18:41
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Sep 2020 13:18:41
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	19 Sep 2020 13:18:02
User entered 'Celebrex'	(b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:29:40
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:43:01
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' answered with 'indication updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:38:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:38:24
User entered 'rheumatoid ARTHRITIS' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	06 Nov 2020 15:38:24
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:59:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Arthritis'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '200'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:17:44



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:17:44

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 13:17:44

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Sep 2020 08:41:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 08:41:41
Data point term sent to Coder	System	19 Sep 2020 13:19:03
User entered 'Sigulair'	(b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:18:54

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 13:18:54

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 13:22:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 13:22:44
Data point term sent to Coder User entered 'Crestor'	System (b) (4), (b) (6)	19 Sep 2020 13:22:03 19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

US3622160

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20



**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:59:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:40:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 13:21:20

**US3622160**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 13:21:20

US3622160

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:13:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 14:15:05
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Dec 2020 15:23:43

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:03
User entered	System	07 Apr 2021 13:20:33
'USA-US085-2021-MRNA-1273-P301000016'		



**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Yes (Y)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Yes (Y)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Susanne'	System	07 Apr 2021 13:20:33



**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Doblecki-Lewis'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered '1120 NW 14th Street'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Miami'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'FL'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered '33136'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
User entered 'US'	System	07 Apr 2021 13:28:15

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 13:28:15

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:03
User entered	System	07 Apr 2021 13:20:33
'USA-US085-2021-MRNA-1273-P301000016'		



**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Yes (Y)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Yes (Y)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'No (N)'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Susanne'	System	07 Apr 2021 13:20:33



**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Doblecki-Lewis'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered '1120 NW 14th Street'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'Miami'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered 'FL'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:28:07
User entered '33136'	System	07 Apr 2021 13:20:33

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
User entered 'US'	System	07 Apr 2021 13:28:15

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 13:28:15

**US3622160**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:13:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:57:10
User entered '07/Apr/2021 09:28'	System	07 Apr 2021 13:28:15



US3622160

Folder: SAE USA-US085-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:29

**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.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 13:28:15